From: Salahuddin, Charles (NIH/NIMH) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AB0B7A9FF74AE28800B0FA85CCE2A4-SALAHUDDINC]
Sent: 3/14/2018 7:58:46 PM
To: Hammersla, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87fb28aa23744c0b855ef0683ac2e8b4-hammerslaa]; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
CC: Wong, Jennifer (NIH/NIMH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4258c7cf58f4945a3df079942c68852-wongje]
Subject: RE: CONFIDENTIAL RE: Inquiry regarding inventions b5,b6

Great. Talk to you then. Thanks again.

Charles

From: Hammersla, Ann (NIH/OD) [E]
Sent: Wednesday, March 14, 2018 3:52 PM
To: Salahuddin, Charles (NIH/NIMH) [E] <salahuddinc@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: RE: CONFIDENTIAL RE: Inquiry regarding inventions b5,b6

10:30 is ok with me. Ann

From: Salahuddin, Charles (NIH/NIMH) [E]
Sent: Wednesday, March 14, 2018 3:32 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>; Rohrbaugh, Mark (NIH/OD) [E] <rohrbaum@od.nih.gov>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: RE: CONFIDENTIAL RE: Inquiry regarding inventions b5,b6

Hi Ann,

Sure. Does 10:30 tomorrow (Thursday) work for you? If so, I will give you call then. Thank you so much.

Charles

Charles Salahuddin, JD, MS
Technology Transfer Patent Specialist
National Institute of Mental Health
Technology Transfer Office
Mail: 35A Convent Drive, Room GE400, MSC 3747
Bethesda, MD 20892
Office: Building 35A, Room GE408
Phone: 301-402-2454
E-mail: salahuddinc@mail.nih.gov

From: Hammersla, Ann (NIH/OD) [E]
Sent: Wednesday, March 14, 2018 3:14 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Salahuddin, Charles (NIH/NIMH) [E] <salahuddinc@mail.nih.gov>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: CONFIDENTIAL RE: Inquiry regarding inventions b5,b6

Charles:

Before sending any internal NIH documents to the VA or to anyone else we should talk.

b5,b6

I can be reached at 301-435- 0745

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, March 14, 2018 1:44 PM
To: Salahuddin, Charles (NIH/NIMH) [E] <salahuddinc@mail.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: RE: Inquiry regarding inventions b5,b6

Ann is the expert but the IRP does not have to report inventions to iEDISON but every extramural institution including government agencies must report NIH funded inventions and patents through iEDISON. If they need information from you to comply with that reporting, then you should assist them.

From: Salahuddin, Charles (NIH/NIMH) [E]
Sent: Wednesday, March 14, 2018 1:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: RE: Inquiry regarding inventions b5,b6

Hi Mark,

In terms of who handles this request, b5
b5
b5 Below is the language from the patent:

This invention was made with government Support under Grant No. b5,b6 awarded by the National Institutes of Health, and a Merit Review Grant from the Department of Veterans Affairs, NIMH Program Grant. The government has certain rights in the invention.

Thank you very much.

Charles

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Wednesday, March 14, 2018 1:20 PM
To: Salahuddin, Charles (NIH/NIMH) [E] <salahuddinc@mail.nih.gov>; Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: RE: Inquiry regarding inventions b5,b6

Charles:

Extramural invention reporting is handling through OER and iEDISON. Ann Hammersla leads that office. I have copied her.

Mark

From: Salahuddin, Charles (NIH/NIMH) [E]
Sent: Wednesday, March 14, 2018 1:07 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Cc: Wong, Jennifer (NIH/NIMH) [E] <jennifer.wong2@nih.gov>
Subject: FW: Inquiry regarding inventions b5,b6

Hi Mark,

Someone from VA tech transfer sent me the email below about two investigators. b5

b5

Would you mind providing guidance about how to respond? Thank you very much.

Charles

Charles Salahuddin, JD, MS
Technology Transfer Patent Specialist
National Institute of Mental Health
Technology Transfer Office
Mail: 35A Convent Drive, Room GE400, MSC 3747
Bethesda, MD 20892
Office: Building 35A, Room GE408
Phone: 301-402-2454
E-mail: salahuddinc@mail.nih.gov

From b6
Sent: Tuesday, March 06, 2018 1:29 PM
To: Salahuddin, Charles (NIH/NIMH) [E] <salahuddinc@mail.nih.gov>
Subject: Inquiry regarding inventions b5,b6

Charles-

It was a pleasure speaking with you. Here is the information I just provided:

Inventors b5,b6

Cited NIH Grant: b5,b6 (There may be other NIH grants associated with the filings, below.)

Relating to:

b5,b6

If you could kindly provide the invention reports associated with the referenced patent filings, it would be much appreciated. Also the scope of the grant awarded, for starters.

Thanks very much for your assistance,

b6
Department of Veterans Affairs
Technology Transfer Program
10P9TT
810 Vermont Ave (NW)
Washington, DC 20420
b6

TECHNOLOGY TRANSFER
PROGRAM

Bringing Research Advancement for Veterans to Everyone (BRAVE!)
https://www.research.va.gov/programs/tech_transfer/default.cfm

From: Silverthorn, Courtney (Fed) [courtney.silverthorn@nist.gov]
Sent: 12/20/2016 4:51:40 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: Bayh-Dole NPRM Comments
Attachments: KEICommentsBayh-DoleRegulationsNIST-9Dec2016.pdf

Hi Mark,
Here is the comment on the NRPM. Please let me know if you have any thoughts.

Thanks,
Courtney

Courtney Silverthorn, Ph.D.
Deputy Director, Technology Partnerships Office
National Institute of Standards and Technology
courtney.silverthorn@nist.gov
O: 301-975-4189
C: b6

KEI
KNOWLEDGE ECOLOGY
INTERNATIONAL

1621 Connecticut Ave NW, Suite 500
Washington, D.C. 20009
+1 (202) 332-2670
http://keionoine.org

9 December 2016

Knowledge Ecology International Comments RE NIST Docket No: 160311229-6229-01: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 81 Fed. Reg. 78,090 (Nov. 7, 2016) (proposed rule to amend 37 C.F.R. §§ 401 and 404)

https://www.regulations.gov/comment?D=NIST-2016-0002-0001

Knowledge Ecology International (KEI) is a not for profit non governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups.

Our comments will focus on the first question posed in the Federal Register notice: "Are there any changes to these regulations, consistent with current law, that you or your organization think would accelerate the transfer of federally funded research and technology to entrepreneurs, or otherwise strengthen the Nation's innovation system?"

1. Transparency of licensing should be improved.

Today we contacted the Army response to a notice in the Federal Register (81 FR 89087) about a potential exclusive license to patents on a vaccine for the Zika virus, to Sanofi, a French pharmaceutical and vaccine company. There are 15 days to respond. The Army was reluctant to provide any details about the terms in the proposed license, including such as items as any description of the technology to be licensed (the patent applications are not public), the royalty rate or any provisions on pricing. We have had similar experiences at the NIH, where the NIH has refused to give out the the address, phone number of names of principles of companies seeking exclusive license to potentially very important medical technologies, let alone the basics on what the companies would pay for the licenses, or how the products would be available to the public on "reasonable terms" (a requirement of 35 USC 201.f). See, for example: http://keionline.org/nih-licenses.

The reports on how patents are worked are generally secret, as are the royalty payments made.

All of this makes a mockery of the public's right to comment on proposed licenses (35 USC 209.e), and makes it difficult to evaluate the licensing practices of federal agencies.

2. We believe agencies do not do adequate evaluations of the scope of exclusivity necessary as required by 35 USC 209.

Under the statute, a federal agency "may grant an exclusive or partially exclusive license on a federally owned invention . . . only if granting the license is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public, and even then, the proposed scope of exclusivity should be "not greater than reasonably necessary to provide the incentive for bringing the invention to practical application . . . or otherwise to promote the invention's utilization by the public."

In previous years, agencies seem to have made some effort to implement this restriction on exclusive rights, for example, by limiting the term of exclusivity for the license on the patents on the HIV/AIDS drug ddI. However, in recent years, as far as we can tell, agencies license for the entire term of the patent even when a shorter period would be sufficient to get a product into the market.

3. We believe agencies systematically ignore the requirement in 35 USC 201(f) that the benefits of inventions be "available to the public on reasonable terms."

Based upon our conversations with NIH and the US Army licensing officials, we believe there is ZERO interest in addressing the issue of what constitutes "reasonable terms". Indeed, the NIH has indicated that by simply making a product available for sale, at any price, the condition of practical application in the statute is satisfied. This was true in the case of Ritonavir, when the US price was 5 to 10 times higher than ANY other high income industrialized country, and for the prostate cancer drug Xtandi, when the price of $129,000 per year was 2 to 4 times higher than ANY other high income industrialized country.

We are concerned that the NIH is licensing patents to a vaccine for the Attenuated Respiratory Syncytial Virus (RSV) Vaccines[1], and the US Army is licensing patents to a vaccine for the Zika virus, without any obligations to make the products available on reason terms to US consumers. Both vaccines are being or have been licensed to the French vaccine and drug manufacturer Sanofi. If the vaccines are successful, we may be faced with very high costs to buy products based upon our own taxpayer funded research.

---

[1] http://keionline.org/node/2445.

A few other examples of where KEI has unsuccessfully sought reasonable pricing include:

- An NIH license for an entire class of Hepatitis C Virus (HCV) medicines to a small biopharmaceutical firm in California, in a case where the NIH declined to disclose the names of the principals in the business or their expertise in bringing HCV medicines to commercialization;[2]

- An NIH license on a class of Chimeric Antigen Receptor T-Cell Receptor (CAR-T) therapies, a form of cancer immunotherapy that will reportedly command high prices (upwards of $200,000 per patient per year) and a large share of the cancer treatment market, to Kite Pharma.[3]

4. Before giving a firm an exclusive right to patents on a drug, vaccine or other key medical invention, the federal government should publish an analysis that estimates the cost the federal government would have incurred in funding clinical trials and other development costs, without granting exclusive rights, and compare those costs of the expected costs of buy the invention from the license holder, when the manufacturer has obtained a legal monopoly.

5. In order to develop more useful evidence to evaluate licensing policies, licenses could and should require transparency of the costs of research and development. For medical inventions, this should include an annual report for R&D outlays, with the company reporting the following information for each clinical trial that it conducts on the patented invention:

a. ClinicalTrials.Gov identifier;
b. Phase;
c. Conditions;
d. Interventions;
e. Title Acronym/Titles;
f. Outcome Measures;
g. Sponsor/Collaborators;
h. Other Study IDs;
i. Expenditures (for that year);

The patent holder should also be required to report:

j. the sales prices, units of sales, and revenues, by country;
k. government subsidies related to the research, reported by year, including:

---

[2] http://keionline.org/node/2219

[3] "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments," http://keionline.org/node/2640; "KEI Comments on NIH Proposed Exclusive License to Kite Pharma for Cancer Treatment," http://keionline.org/node/2648; and "Kite Pharma Press Releases & News Stories Related to Relationship with National Cancer Institute," http://keionline.org/node/2644.

   i. grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;
   ii. tax credits associated with R&D for the product, including the orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and
   iii. other government R&D subsidies;

6.. For medical inventions, agencies should be required to consider including provisions that would limit the length of exclusivity, when life of patent exclusivity is and excessive and costly incentive. For example, for some drugs or vaccines, where significant development costs are already paid for by the government, licenses could including provisions such as the following:

> The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $1 billion in cumulative global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light of the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

7. To ensure that prices for products are “reasonable” -- the standard in 35 USC 201(f) -- and do not discriminate against US residents, licenses should limit the price of the product to no more than the median price of other high income countries. For example, using language such as:

> The [agency] will normally expect the licensee to make products available to the public in the United States at prices no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

8. In some cases, it will be appropriate to include other standards for the reasonableness of prices, including to ensure that products are reasonably affordable.

For example, for drugs, health insurance plans often impose co-payments as high as 20 percent of the sale price of the drug. For such a co-payment to be affordable, the co-payment should be reasonable compared to the wages of a worker, after paying for taxes, food, shelter and other living expenses. The IRS considers medical expenses extraordinary if they exceed 10 percent of your adjusted gross income, or 7.5 percent for persons 65 or over. One could set a ceiling on prices for a single drug at 37.5 percent of the adjusted gross income (so that 20 percent of the drug was equal to 7.5 percent of the workers adjusted gross income), using the median wage for all employees (less than $36,000 per year), or a lower figure, such as the minimum wage (less than $15,000 per year) or some multiple of the federal poverty level ($11,880 per year in 2016 for a single person), to make medicines more universally affordable.

37.5 percent of twice the federal poverty level would result in a cap in prices of $8,910 per year.

9. Licenses on medicines, vaccines and other health related inventions should require that products are available and affordable in developing countries, especially those with per capita incomes of less than one third of the U.S. per capita income.

We believe that the above provisions are consistent with the intent of the Bayh-Dole Act, which has as its "policy and objective" to promote innovation while protecting "the public against nonuse or unreasonable use of inventions." 35 U.S.C. § 200.

Sincerely,

James Love
Knowledge Ecology International
james.love@keionline.org
+1.202.332.2670
http://keionline.org

From: Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HAMMERSLAA]
Sent: 12/21/2016 8:25:22 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: FW: Bayh-Dole NPRM Comments

Comments/Edits?

From: Hammersla, Ann (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 3:42 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: FW: Bayh-Dole NPRM Comments

How about: b5

b5

From: Hammersla, Ann (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 12:20 PM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: RE: Bayh-Dole NPRM Comments

Hello Mark: Yes I have talked with NIST. b5
b5
b5 Ann

From: Rohrbaugh, Mark (NIH/OD) [E]
Sent: Tuesday, December 20, 2016 12:10 PM
To: Hammersla, Ann (NIH/OD) [E] <hammerslaa@mail.nih.gov>
Subject: FW: Bayh-Dole NPRM Comments
Importance: High

Ann:

NIST b5

Mark

From: Silverthorn, Courtney (Fed) [mailto:courtney.silverthorn@nist.gov]
Sent: Tuesday, December 20, 2016 11:52 AM
To: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>
Subject: Bayh-Dole NPRM Comments
Importance: High

Hi Mark,
b5 Please let me know if you have any thoughts.

Thanks,

Courtney

Courtney Silverthorn, Ph.D.
Deputy Director, Technology Partnerships Office
National Institute of Standards and Technology
courtney.silverthorn@nist.gov
O: 301-975-4189
C: b5

Report of the UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

Promoting innovation and access to health technologies

September 2016

UNITED NATIONS SECRETARY-GENERAL'S
HIGH-LEVEL
PANEL ON ACCESS
TO MEDICINES

This is an independent report prepared by the High-Level Panel on Access to Health Technologies, convened by the United Nations Secretary-General in November 2015. The opinions expressed in this report are the authors' own and do not necessarily reflect the views of the UN Secretary-General, the Executive Office of the United Nations Secretary-General or the United Nations.

Secretariat hosted by the United Nations Development Programme	
Head	Mandeep Dhaliwal & Tenu Avafia, United Nations Development Programme
Project Manager:	Richard Delate
Senior Advisors:	Carlos Passarelli & Simon Bland, Joint United Nations Programme on HIV/AIDS
Senior Researchers:	Katie Kirk & Lisa Hamelmann
Researchers:	Firass Halawi, Patrick Tindana & Sarah Greenbaum
Project Associate:	Desiree Gomez
Project Support:	Katrina Geddes, Ashley Andreou & HIV, Health and Development Group, UNDP
Writing, Editing and Design Support:	Judith Levine, Roy Small, Julia Stewart, Lushmo & Paprika Communications
Communications:	Global Health Strategies

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TABLE OF CONTENTS

PREFACE 3
ABBREVIATIONS AND ACRONYMS 4
GLOSSARY 5
EXECUTIVE SUMMARY 7
INTRODUCTION 12
1. HEALTH TECHNOLOGY INNOVATION AND ACCESS 13
  1.1 Multiple barriers to access 15
  1.2 Policy incoherencies 16
2. INTELLECTUAL PROPERTY LAWS AND ACCESS TO HEALTH TECHNOLOGIES 21
  2.1 Voluntary licences 22
  2.2 TRIPS flexibilities 22
  2.3 National coherence 24
  2.4 Limitations to the use of TRIPS flexibilities 24
  2.5 Intellectual property generated from publicly-funded research 26
  2.6 Recommendations 27
3. NEW INCENTIVES FOR RESEARCH AND DEVELOPMENT OF HEALTH TECHNOLOGIES 29
  3.1 Delinking the costs of research and development from the end product 29
  3.2 Priority setting and coordination 30
  3.3 Financing 30
  3.4 Recommendations 31
4. GOVERNANCE, ACCOUNTABILITY AND TRANSPARENCY 33
  4.1 Governance and accountability 33
  4.2 Transparency 35
  4.3 Recommendations 36
END NOTES 38

Annex 1: Commentaries 53
Annex 2: How the High-Level Panel reached its conclusions 64
Annex 3: The United Nations Secretary-General's High-Level Panel on Access to Medicines 65
Annex 4: Terms of Reference: The United Nations Secretary-General's High-Level Panel on Access to Medicines 66
Annex 5: The Expert Advisory Group 68

PREFACE

Never in the past has our knowledge of science been so profound and the possibilities to treat all manner of diseases so great. Many sources of transmissible and non-transmissible diseases have been identified, and therefore prevention, including the fight against bacteria, viruses and parasites, has improved dramatically. New generations of medicines and their combinations are treating patients whose prognosis some years ago would have been fatal. The development of medical devices, the ability to combine new materials and use micro- and even nanotechnology and computer science are increasing the safety of interventions and replacing natural functionalities. Progress in fundamental research is nourishing an exceptional phase of development of medicines, vaccines, diagnostics and medical devices.

And yet, many people and communities in need of effective prevention methods, life-enhancing and life-saving treatments and rehabilitation do not receive them. In some cases, populations live in such unhealthy environments that they remain at daily risk of becoming or staying ill. Or, their health services are not accessible or so poorly organized and equipped that they cannot deliver what is necessary. In other cases, vaccines, diagnostics and medicines have not yet been developed for defeating the diseases from which they suffer. Many face prices that are too high, either for those who are paying out-of-pocket or for health systems at risk of rationing treatments. Availability, affordability and adaptation to specific settings and patient categories remain problematic in many regions and for many populations throughout the world. Meanwhile, new threats – new diseases and drug-resistant diseases – are emerging, for which global solutions must be found urgently.

In short, on one hand we are witnessing the immense potential of science and technology to advance medicine and healthcare, while on the other hand we are severely challenged by gaps and failures in addressing disease burdens and emerging diseases in many countries and communities.

On 19 November 2015, United Nations Secretary-General Ban Ki-moon announced the creation of a High-Level Panel on Innovation and Access to Health Technologies (the 'High-Level Panel for short). In outlining our mandate, the Secretary-General called upon us to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."

In line with the goals of United Nations Member States as articulated in the 2030 Agenda for Sustainable Development, and in particular in support of attaining Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages," the scope of the High-Level Panel's mandate was simultaneously ambitious and limited. It was limited because we were not assigned the task of analysing all the reasons why health technologies are not available or affordable, even if we were always conscious of the many unmet obligations with regard to the right to health. It was ambitious because we aimed to propose real solutions that would help promote research, development, innovation and could increase access to medicines, vaccines, diagnostics and medical devices.

Building on positive initiatives developed in collaboration with public and private partners during the last decades, recognizing the importance of mitigating trade rules and public health obligations (as did the World Trade Organization when adopting an agreement on trade-related aspects of intellectual property and the Doha Declaration), aware of the necessity to build coherence and accountability both nationally and internationally in the achievement of public health objectives, we hope to have contributed to further positive change in innovation and access to health technologies.

The High-Level Panel came together as a diverse groups of individuals from various backgrounds, experiences and continents. Discussions took place in an atmosphere of mutual respect, with each of us recognizing that the world community as a whole, and each one of us, shares a stake in this subject matter, and that we can and must do better. Even if members of the High-Level Panel did not agree on every detail of the report, we reached broad consensus on most aspects. And most importantly we are unanimous on the need to act, and to act now.

Members of the High-Level Panel were far from alone in their endeavours. Our deliberations were informed by and benefited from a broad consultative process, which included a generous response to a public call for contributions that netted 182 submissions, many of which were of a high quality. Hearings and Global Dialogues were held in London and Johannesburg in March 2016 to examine the proposals and incorporate the views and inputs from concerned parties and affected communities. The High-Level Panel was ably supported by an Expert Advisory Group, under the dedicated chairmanship of Justice Michael Kirby. This group brought together the knowledge and experience of expertise from civil society, industry, academia and from many United Nations and multilateral organizations. The members of the High-Level Panel would like to extend their deepest gratitude to all contributors, whom we unreservedly acknowledge for enlivening and enriching our debates and strengthening the recommendations.

To the extent possible, we have grounded our recommendations in concrete and actionable steps. We hope the report may serve stakeholders – governments, policy-makers, business leaders, representatives of international organizations and civil society alike – as a useful point of reference and evidence to support a stepped up mobilization for improving health and well-being for all.

Ruth Dreifuss
Co-chair

Festus Gontebanye Mogae
Co-chair

ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immune deficiency syndrome
AMR	Antimicrobial resistance
ARV	Antiretroviral
CAFTA-DR	Dominican Republic-Central America Free Trade Agreement
CESCR	United Nations Committee on Economic, Social and Cultural Rights
CEWG	Consultative Expert Working Group on Research and Development: Financing and Coordination (WHO)
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health (WHO)
DNDi	Drugs for Neglected Diseases initiative
EID	Emerging infectious disease
EML	Essential Medicines List
EPA	Economic Partnership Agreement
FDA	Food and Drug Administration (United States)
FTA	Free trade agreement
GAP-AMR	Global Action Plan on Antimicrobial Resistance (WHO)
GARD	Global Antibiotic Research and Development Partnership (WHO-DNDi)
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism (WHO)
HIV	Human immunodeficiency virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICTRP	International Clinical Trials Registry Platform
ICTSD	International Centre for Trade and Sustainable Development
INN	International non-proprietary name
IP	Intellectual property
LDC	Least developed country
MDG	Millennium Development Goal
MDR-TB	Multi-drug-resistant tuberculosis
MPP	Medicines Patent Pool
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organization
NIH	National Institutes of Health (United States)
NTD	Neglected tropical disease
OECD	Organization for Economic Co-operation and Development
OHCHR	Office of the United Nations High Commissioner for Human Rights
PDP	Product development partnership
PEPFAR	United States President's Emergency Plan for AIDS Relief
R&D	Research and development
SDG	Sustainable Development Goal
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases (UNICEF, UNDP, World Bank, WHO)
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
V3P	Vaccine Product, Price and Procurement web platform (WHO)
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

GLOSSARY[1]

Bayh-Dole Act: U.S. legislation enacted in 1980, which created a uniform federal policy allowing universities and research institutions to elect to retain title, through patent protections, to inventions created in whole or in part from federal funding.

Biologic: Any virus, therapeutic serum, toxin, antitoxin, hormone or protein, including monoclonal antibodies or similar products used to diagnose, prevent, treat or cure a disease or condition.

Biomedical: The field of science, industry and research that applies the natural sciences, especially the biological and physiological sciences, to clinical medicine to better understand disease processes and develop therapies for the prevention and treatment of diseases and conditions that cause illness.

Biosimilar: A biologic product sufficiently similar in quality, safety and efficacy to an already licensed and market-approved biologic product that is shown to have no clinically meaningful differences from the original biologic product.

Biotechnology: The use of biological processes, organisms or systems to manufacture treatments intended to improve the quality of human life. Biotechnology is an interdisciplinary science-based technology that combines knowledge from various fields, such as microbiology, biochemistry, genetics, process technology and chemical engineering.

Bolar exemption: A legal exception that permits the use of a patented invention before the patent expires for the purposes of obtaining marketing approval of a generic product for commercialization once the patent expires.

Clinical trial: A research study in which candidate therapies are tested on human subjects to identify their clinical, pharmacological or other effects, adverse reactions and absorption, distribution, metabolism and excretion in the human body in order to ascertain their safety and efficacy. There are four phases of clinical trials: Phase I (a candidate therapy is given to a small group of people for the first time); Phase II (the candidate therapy is given to a larger group of people to further evaluate its safety and efficacy); Phase III (the candidate therapy is given to larger groups of people to confirm its efficacy, monitor side effects, compare it to commonly used treatments and collect safety information); and Phase IV (post-marketing studies gather information on the health technology's efficacy in various populations and a side-effect associated with long-term use).

Data exclusivity: A legal regime in which, for a specified period of time, national regulatory authorities are barred from the use of clinical studies and data developed by an originator company to register the generic equivalent of a medicine. Generic manufacturers seeking regulatory approval within a period of data exclusivity must conduct new clinical trials to prove the safety and efficacy of their equivalent products.

Delinkage: A term used to describe a key characteristic of any financing model of innovation characterized by the uncoupling of R&D costs and consumer prices for health technologies. Examples of delinkage models include grants, prizes and advance market commitments, among others.

Doha Declaration on the TRIPS Agreement and Public Health: The World Trade Organization (WTO) Declaration on the TRIPS Agreement and Public Health (2001), which affirmed, inter alia¸ that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

Evergreening: A term used to describe patenting or marketing strategies to extend the period of patent protection or effective period of market exclusivity, which are considered to be unjustifiable and therefore abusive. In some cases, for example, this might involve the filing of multiple, often successive, patent applications on minor and insignificant variants or indications of the same compound

Health technology: Medicines, vaccines, diagnostics and medical devices used to prevent, diagnose and treat health problems.

Neglected diseases: Diseases for which there is a lack of sufficient medical innovation, resulting in inadequate, ineffective or non-existent means to prevent, diagnose and treat them. The lack of sufficient medical innovation is often rooted in an absence of market incentives owing to the low purchasing power of the populations disproportionately affected by such conditions.

Originator: A term that generally refers to the product that was first authorized worldwide for marketing (normally as a patented product). The term also refers to the company that commercialized the originator product.

Orphan disease: A disease that affects only small numbers of individuals. The threshold number varies from country to country. An orphan disease may affect fewer than 200,000 individuals (United States), fewer than 50,000 (Japan) or less than 2,000 (Australia). Definitions vary from diseases affecting about 1 to 8 in 10,000 individuals.

Paragraph 6 decision: An agreement reached by WTO Members on 30 August 2003 in response to paragraph 6 of the Doha Declaration. The paragraph 6 decision grants waivers of the TRIPS Agreement Article 31(f) and (h) to permit the manufacture of pharmaceutical products under a compulsory licence within the territory of a WTO Member predominantly for export to another WTO Member that lacks the requisite domestic manufacturing capacity. With this solution, subject to a number of conditions, the predominant or total consignment of pharmaceutical products manufactured under compulsory licence may be exported to another country.

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[1] The definitions in this glossary are not designed to provide a technical description of every aspect of national and international legal provisions where these are applicable. Rather, the glossary was developed as a general guide for non-technical readers for terms used in the report.

Patent: A statutory, time-limited exclusive right granted by a national authority to prevent others from legally making, using, offering for sale or selling a qualifying invention.

Patentability criteria: Requirements that must be satisfied before a patent is awarded. These are (1) subject matter for eligibility, (2) novelty, (3) an inventive step and (4) industrial application. The precise nature of these requirements is not defined in the TRIPS Agreement and it is up to countries to define these in their laws and policies.

Patent pools: An agreement among patent holders to voluntarily license a set of their patents to one another or to third parties. Patent pools are often administered or managed by institutional frameworks to facilitate the negotiation of such agreements.

Publicly-funded research: For the purposes of this report, this refers to research that is primarily or totally financed by government funds and disseminated through government bodies as well as academic and research institutions.

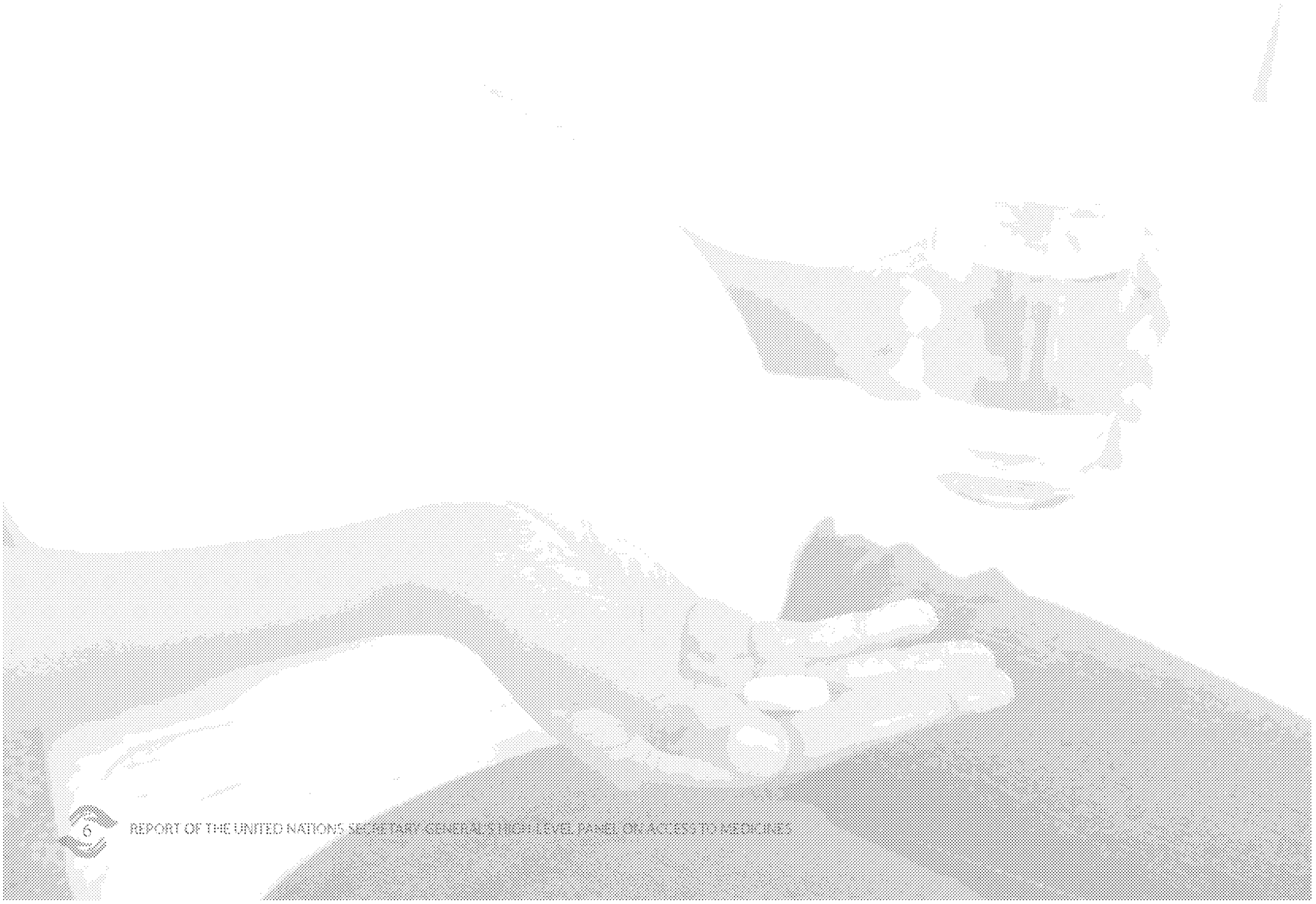
Test data protection: A legal obligation imposed by the TRIPS Agreement on WTO Members to protect undisclosed test data from unfair commercial use. Such data is required to be submitted as a condition of approving the marketing of a pharmaceutical or agricultural chemical product. (Contrast to data exclusivity above).

TRIPS: The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.

TRIPS flexibilities: A term used broadly to describe a set of norms, rules and standards that allow variations in the implementation of the TRIPS Agreement obligations, including limits on the exercise of intellectual property rights.

Voluntary licence: A licence granted by a patent holder to a third party to produce and/or market and distribute a patented product, usually in exchange for a royalty on net sales and certain other conditions (for example, geographical restrictions on where the product can be sold).

WHO Essential Medicines List: The World Health Organization (WHO) Essential Medicines List (EML) contains therapeutic medicines that satisfy the priority healthcare needs of the global population. Medicines are deemed 'essential' by WHO following an evaluation of disease prevalence, public health relevance, evidence of clinical efficacy and safety and comparative costs and cost-effectiveness. The WHO EML is often used as a guide in the development of national essential medicines lists.



EXECUTIVE SUMMARY

In September 2015, 193 Member States of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) 3 that aims to ensure healthy lives and promote the well-being of all people of all ages. SDG 3 is an important vehicle for realizing the right to health and the right to share in the benefits of scientific advancements, whose affirmation dates back to the Charter of the United Nations (1945), the Universal Declaration of Human Rights (1948) and the Constitution of the World Health Organization (WHO) (1948). These rights are also enshrined in the International Covenant on Economic, Social and Cultural Rights (1966) and various other international treaties, declarations and national laws, including at least 115 constitutions.

Consistent with the vision of the 2030 Agenda and a recommendation by the Global Commission on HIV and the Law that the United Nations Secretary-General establish a high-level body to propose ways of incentivizing health technology innovation and increasing access to medicines and treatment, Secretary-General Ban Ki-moon, in November 2015, announced the appointment of a High-Level Panel on Innovation and Access to Health Technologies.

In keeping with the commitment of United Nations Member States to enhance policy coherence for sustainable development, the High-Level Panel's terms of reference called for it to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies," among other things. In accordance with the principle of universality that underpins the 2030 Agenda and its aspiration to leave no one behind, the High-Level Panel views innovation and access to health technologies as a multi-dimensional and global problem that affects all countries.

Health technology innovation and access

Over the last few decades, medical innovation has dramatically improved the lives of millions of people across the globe. Vaccines have significantly reduced the prevalence of diseases, ranging from polio to human papillomavirus. Antiretroviral medicines have greatly improved the lives of people living with the Human Immunodeficiency Virus (HIV). Personalized strategies based on molecularly-targeted medicines are likely to become central to cancer treatment in the future. Despite this noteworthy progress, millions of people continue to suffer and die from treatable conditions because of a lack of access to health technologies.

Investment in research and development (R&D) of health technologies does not adequately address a number of important health needs. In some cases, the cause lies in inadequate resourcing of R&D for diseases where the market does not provide sufficient return on investment. Antibiotics typically offer little pecuniary reward for years of often costly research. In these circumstances, experts warn that drug-resistant viruses, bacteria, parasites and fungi could cause 10 million deaths a year worldwide by 2050. The current model of medical innovation is ill-equipped to respond to the increasing emergence of infectious diseases, such as Ebola and Zika. Meanwhile, neglected tropical diseases (NTDs) continue to receive inadequate funding for R&D and access to health technologies, despite more than a billion people living with one or more NTD. The situation is driven by the relatively low purchasing power of people disproportionately affected by such conditions.

There are many reasons why people do not get the healthcare they need, including, inter alia, under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, regulatory barriers, poor health education, unavailability of health insurance, exclusion, stigma, discrimination and exclusive marketing rights. The High-Level Panel acknowledges the importance of addressing these multiple determinants to health technology innovation and access. However, the High-Level Panel's mandate is focused on one aspect of a complex challenge: the incoherencies between international human rights, trade, intellectual property (IP) rights and public health objectives.

Policies and agreements related to human rights, trade, intellectual property rights and public health were developed with different objectives at different times. State obligations include duties not only to respect, but to protect and fulfil the right to health. This requires taking proactive measures to promote public health. As reaffirmed by a recent Human Rights Council resolution, ensuring access to medicines, and particularly to essential medicines, is a fundamental element of these obligations. Trade rules and intellectual property laws were developed to promote economic growth and incentivize innovation. On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to the public health objectives of World Trade Organization (WTO) Members.

The adoption of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994 ushered in a new and unprecedented era of global intellectual property norms and created a new standard of intellectual property protection and enforcement. However, negotiators included safeguards, or 'flexibilities,' within the TRIPS Agreement that could be used by signatories to tailor national intellectual property regimes so that countries could fulfil their human rights and public health obligations (for instance, laws and regulations regarding competition, government procurement and medicines). The proliferation of free trade agreements containing expansive patent and test data protections on health technologies, which exceed the minimum standards for intellectual property protection required by the TRIPS Agreement (so-called 'TRIPS-plus' provisions), may impede access to health technologies. Also, an uneven application of health and trade policy within and among states can create tensions that fuel policy incoherence.

Intellectual property laws and access to health technologies

Public health-sensitive intellectual property rules and mechanisms can help address the misalignment between profit-driven innovation models and public health priorities. Voluntary licences, entered into between right holders and third parties to facilitate the market entry of more affordable health technologies, have helped to lower treatment costs in many countries. TRIPS flexibilities – for example, the freedom to determine patentability criteria and further define concepts such as "novelty," "inventive step" and "industrial applicability" – can ensure that patents are only awarded for genuine innovation. Similarly, the ability to determine the terms upon which compulsory licences are issued allows governments to fulfil their human rights obligations by securing the availability and affordability of health technologies. Many governments have not used the flexibilities available under the TRIPS Agreement for various reasons ranging from capacity constraints to undue political and economic pressure from states and corporations, both express and implied. Political and economic pressure placed on governments to forgo the use of TRIPS flexibilities violates the integrity and legitimacy of the system of legal rights and duties created by the TRIPS Agreement, as reaffirmed by the Doha Declaration. This pressure undermines the efforts of states to meet their human rights and public health obligations. The use of TRIPS flexibilities may also be impeded by the proliferation of bilateral and regional free trade agreements containing TRIPS-plus provisions.

The policies of public funders of health technology R&D can also play an important role in enhancing health technology innovation and access. The United States, for instance, holds a central position in health technology innovation. The country's R&D and access policies influence other actors, including private and public sector donors and foundations, and have an impact on access to the fruits of technology worldwide. The introduction of the 1980 Bayh-Dole Act in the United States significantly changed academic research by allowing universities and public research institutions to patent the results of federally-funded research and license private enterprises to develop them. However, limiting access to academic discoveries can obstruct follow-on innovation and force taxpayers to pay twice for the benefits of publicly-funded research. Strong, enforceable policies on data sharing and data access should be a condition of public grants. Public funding agencies should strongly encourage patenting and licensing practices that benefit public health, including the use of non-exclusive licences, the donation of intellectual property rights, participation in public sector patent pools and other mechanisms that maximize innovation while promoting access. Open models of innovation can also lower entry hurdles and accelerate the pace of development of health technologies, including those needed to combat emerging infectious diseases.

New incentives for research and development of health technologies

Market-driven R&D has been credited by some for producing a number of important health technologies that have improved health outcomes significantly worldwide. However, significant gaps in health technology innovation and access persist. Under the prevailing model, the biomedical industry, with the help of intellectual property and data protections, in addition to benefiting from public funding for research, recoups the costs of its R&D and marketing through high product prices protected by patent monopolies and data and market exclusivities. As a result, new technologies are rarely developed for health conditions which cannot deliver high returns, such as bacterial infections that only require antibiotics. Rare diseases that affect comparatively small proportions of the population have not traditionally attracted investments although this is changing.

Various efforts are being undertaken by governments, philanthropic organizations, international entities, civil society groups and the private sector to resolve the incoherence between market-driven approaches and public health needs. However, such efforts tend to be fragmented, disparate and insufficient to deal with priority health needs on a sustainable, long-term basis. A much greater effort must be directed to supplementing the existing market-driven system by investing in new mechanisms that delink the costs of R&D from the end prices of health technologies.

Identification of global health priorities is necessary to efficiently distribute scarce health resources, to substantially improve the health status of populations and to enhance global preparedness for future health crises. The current patchwork of public, private and philanthropic funding cannot sufficiently and sustainably improve access to health technologies. Greater and more sustainable financial commitments are needed from both the public and private sectors and should be coordinated to achieve maximum utility and effect.

Governance, accountability and transparency

Good governance, strong and concrete accountability mechanisms and greater transparency are decisive enablers of the 2030 Agenda. An important factor behind the incoherence between human rights, trade, intellectual property and public health lies in the diverse accountability mechanisms and transparency levels of these different, but overlapping spheres. Trade- and intellectual property-related accountability mechanisms are typically regulated by the WTO Dispute Settlement Understanding and dispute settlement provisions found in free trade and investment agreements. In contrast, human rights and public health accountability mechanisms are characterized by varying and often limited degrees of precision, legal weight and enforceability.

Transparency is necessary to hold governments, the private sector and other stakeholders accountable for the impact of their actions on access to health technologies. However, accurate and comprehensive information on the costs of R&D, marketing, production and distribution, as well as the end prices of health technologies, can be difficult to aggregate. Existing public databases of health technology prices managed by international organizations and civil society groups, while laudable, tend to be limited in scope and accuracy, in part because of discounts, mark-ups, taxes and regional pricing differences. The absence of transparency in clinical trial data and a lack of coordination within national drug regulatory authorities can contribute to delays in the registration of new health technologies. Procurement decisions and generic manufacturing are often delayed by the absence of clear, accurate and up-to-date information on existing and expired patents. Moreover, trade and investment agreements containing TRIPS-plus provisions are often negotiated in secret. This lack of transparency makes it difficult to hold governments and other stakeholders accountable for the impact of their policies and actions on innovation and access to health technologies.

The incoherencies between the right to health, trade, intellectual property and public health objectives can only be resolved using robust and effective accountability frameworks that hold all stakeholders responsible for the impact of their decisions and actions on innovation and access to health technologies.

Recommendations

Intellectual property laws and access to health technologies

World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. More specifically:

TRIPS flexibilities and TRIPS-plus provisions

World Trade Organization (WTO) Members must make full use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities as confirmed by the Doha Declaration to promote access to health technologies when necessary.

WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that are in the best interests of the public health of the country and its inhabitants. This includes amending laws to curtail the evergreening of patents and awarding patents only when genuine innovation has occurred.

The United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should cooperate with one another and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.

These multilateral organizations should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.

WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be reported to by the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure which includes taking punitive measures against offending WTO Members.

Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.

Publicly-funded research

Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research.

Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices. Such practices may include publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others. Sufficient incentives must be in place in these practices to make it attractive for developers to underwrite the cost of bringing a product to market at affordable prices that ensure broad availability.

Universities and research institutions that receive public funding should adopt policies and approaches that catalyse innovation and create flexible models of collaboration that advance biomedical research and generate knowledge for the benefit of the public.

New incentives for research and development of health technologies

It is imperative that governments increase their current levels of investment in health technology innovation to address unmet needs.

Stakeholders, including governments, the biomedical industry, institutional funders of healthcare and civil society, should test and implement new and additional models for financing and rewarding public health research and development (R&D), such as the transaction taxes and other innovative financing mechanisms.

Building on current discussions at the WHO, the United Nations Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all. The Convention should focus on public health needs, including but not limited to, innovation for neglected tropical diseases and antimicrobial resistance and must complement existing mechanisms.

As a preparatory step, governments should form a Working Group to begin negotiating a Code of Principles for Biomedical R&D. The principles would apply to public R&D funds and should also be adopted by private and philanthropic funders, product development partnerships, universities, the biomedical industry and other stakeholders. Governments should report annually on their progress in negotiating and implementing a Code of Principles as a preparatory step to negotiating the Convention in the United Nations General Assembly.

Governance, accountability and transparency

Governments

Governments must review the situation of access to health technologies in their countries in light of human rights principles and States' obligations to fulfil them, with assistance from the Office of the United Nations High Commissioner for Human Rights (OHCHR) and other relevant United Nations entities. The results of these assessments should be made publicly available. Civil society should be financially supported to submit their own shadow reports on innovation and access to health technologies. Such national reviews should be repeated at regular intervals.

Governments should strengthen national level policy and institutional coherence between trade and intellectual property, the right to health and public health objectives by establishing national inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access. Appropriate member/s of the national executive who can manage competing priorities, mandates and interests should convene such bodies. The deliberations and decisions of such groups should operate with a maximum of transparency. Civil society should be financially supported to participate and submit their shadow reports on innovation and access to health technologies.

Multilateral organizations

The United Nations Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access. Challenges and progress on innovation and access to health technologies under the ambit of the 2030 Agenda, as well as progress made in implementing the recommendations of this High-Level Panel, should be monitored by this body. Membership should comprise of governments, representatives from United Nations and multilateral organizations, civil society, academia and the private sector.

The United Nations Secretary-General should establish an inter-agency taskforce on health technology innovation and access. This taskforce, operating for the duration of the SDGs, should work toward increasing coherence among United Nations entities and relevant multilateral organizations like the WTO. The taskforce, charged with overseeing the implementation of the High-Level Panel's recommendations should be coordinated by the United Nations Development Group and report annually to the United Nations Secretary-General on progress made in enhancing United Nations system-wide coherence on innovation and access to health technologies.

The United Nations General Assembly should convene a Special Session, no later than 2018, on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access as set out in the 2030 Agenda. Civil society should be financially supported to participate and submit their reports on innovation and access to health technologies at this Special Session.

Private sector companies

Biomedical private sector companies involved in health technology innovation and access should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.

Private sector companies should have a publicly available policy on their contribution to improving access to health technologies setting out general and specific objectives, timeframes, reporting procedures and lines of accountability and a governance system that includes direct board-level responsibility and accountability on improving access to health technologies.

R&D, production, pricing and distribution of health technologies

Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to: (1) the costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and (2) any public funding received in the development of the health technology, including tax credits, subsidies and grants.

Building on the Global Price Reporting Mechanism (GPRM), V3P and others, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.

Clinical trials

Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the WHO Clinical Trials Registry Platform, clinical trials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.

To facilitate open collaboration, reconstruction and reinvestigation of failures, governments should require that study designs and protocols, data sets, test results and anonymity-protected patient data be available to the public in a timely and accessible fashion. Those undertaking clinical trials must not prevent researchers from publishing their findings.

Patent information

Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include: (1) standard international common names for biological products; (2) international non-proprietary names for products, either as known at the time of application or after the granting of a patent; and (3) dates of grant and expiry.

INTRODUCTION

In September 2015, 193 Member States of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) 3 that aims to ensure healthy lives and to promote the well-being of all people of all ages. SDG 3 comes with specific targets for supporting research, development and access to essential medicines and vaccines.[1] The 2030 Agenda also reinforces the importance of human rights, including the right to health and the right to share in the benefits of scientific advancements, whose affirmation dates back to the Charter of the United Nations (1945),[2] the Universal Declaration of Human Rights (1948)[3] and the World Health Organization (WHO) Constitution (1948).[4] These rights are also found in numerous global and regional treaties and in many national constitutions.[5] [6] Despite the presence of these rights and the commitment of countries to advance public health objectives, millions of people do not have access to the health technologies that form a core component of the right to health. The reasons for this are complex and numerous. The United Nations Secretary-General released a synthesis report in 2015 identifying some of the underlying causes. One of the main causes cited in the report was incoherence between current modes of international governance in trade, finance and investment on the one hand and norms and standards for labour, the environment, human rights, equality and sustainability on the other.[7] This report called for steps to be taken to ensure that "global intellectual property regimes and the application of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are fully consistent with and contribute to the goals of sustainable development."[8]

Consistent with the vision of the 2030 Agenda, including a commitment by United Nations Member States to enhance policy coherence for sustainable development and a recommendation by the Global Commission on HIV and the Law that the United Nations Secretary-General establish a high-level body to propose ways of incentivizing health technology innovation and increasing access to treatment,[9] Secretary-General Ban Ki-moon, in November 2015, announced the appointment of a High-Level Panel on health technology innovation and access, or for short, the 'High-Level Panel on Access to Medicines' (the High-Level Panel). The High-Level Panel was comprised of 15 eminent individuals with an understanding of a broad range of legal, commercial, trade, public health and human rights issues central to promoting innovation and access to health technologies. Their work was supported by a 25-member Expert Advisory Group constituted from academia, the private sector, civil society and relevant United Nations and international organizations, such as the World Trade Organization (WTO).

The High-Level Panel builds on previous and existing work in the field of health technology innovation and access. These include developments at WHO, the Human Rights Council and the United Nations General Assembly since the release of the report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). These initiatives have guided governments when addressing the important challenges related to health technology innovation and access to prevent and treat various infectious and noncommunicable diseases.

The High-Level Panel's mandate includes a request by the United Nations Secretary-General to: *"Review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."*[10]

In accordance with the principle of universality that underpins the 2030 Agenda and its aspiration to leave no one behind,[11] the High-Level Panel views access to medicines, vaccines, diagnostics and related health technologies as a serious, multi-dimensional global problem, with challenges that affect all people and all countries. Adopting a broad approach is necessary at this juncture in history, as the High-Level Panel recognizes that the costs of health technologies are rising globally and are being felt by individuals and by public and private insurance schemes in both wealthy and resource-constrained countries alike. These rising costs have the potential to push more people into poverty. With populations living longer, the need for health technologies, especially for noncommunicable diseases, only grows, placing a strain on budgets to meet greater healthcare burdens—not to mention the health-related threats of a global nature, such as increasing incidences of resistance to antibiotics and emerging transmissible diseases.

The report is structured in four chapters:

- **Chapter one *(Health Technology Innovation and Access)*** examines the problem at the heart of the High-Level Panel's mandate: asymmetries of power between institutions and the incoherencies in law, policy and practice between the right to health, international trade and intellectual property rules and public health objectives and their effect on health technology innovation and access.

- **Chapter two *(Intellectual Property Laws and Access to Health Technologies)*** discusses the prevalent international intellectual property regime, the flexibilities contained therein that can be used to promote access to health technologies and examines why flexibilities have not been systematically used, as well as developments such as free trade agreements that may impede the use of TRIPS flexibilities.

- **Chapter three *(New Incentives for Research and Development of Health Technologies)*** highlights the role that increased coordination, priority setting and R&D can play in systematically addressing unmet health needs and examines some of the new models that can be used by various actors.

- **Chapter four *(Governance, Accountability and Transparency)*** examines governance and accountability mechanisms needed to promote health technology innovation and access, including the roles of key stakeholders. It highlights the need for transparency in the various stages of health technology innovation and access in order to strengthen coherence at all levels of policies and actions.

1. HEALTH TECHNOLOGY INNOVATION AND ACCESS

The last half-century has borne witness to a fertile period of medical innovation that has improved the health and lives of millions. During this time, a successful polio vaccine was developed and contributed to a 99% reduction in cases worldwide.[12] In 1996 triple-drug anti-retroviral (ARV) therapy was recommended, transforming the Acquired Immune Deficiency Syndrome (AIDS) from a death sentence to a manageable chronic disease.[13] Investments by industry, generic competition and collaborations between industry, philanthropy, governments, non-governmental organizations (NGOs) and the tenacious advocacy by patients and their allies have resulted in 17 million people accessing life-saving HIV treatments.[14] The introduction of a vaccine for rotavirus in 2006 has resulted in a dramatic reduction in deaths and hospitalizations of babies and young children.[15] The disfiguring, disabling mosquito-borne disease lymphatic filariasis (also known as elephantiasis), primarily endemic to Africa, can now be prevented with a single, annual, two-medicine treatment and medicines donated by manufacturers, delivered through mass administration programmes, have begun to slow infection and transmission in affected countries.[16] Scientists are developing breast cancer and lupus therapies based on discoveries in genetics,[17] as well as stem cell-based medicines.[18] Deadly and formerly incurable diseases are meeting their nemeses. Introduced in 2014, sofosbuvir, in combination with daclatasvir, cures almost all hepatitis C patients over a remarkably short period of time, with minimal side effects.[19] These advances, along with improvements in nutrition and sanitary conditions, have contributed to improved health outcomes across the world.

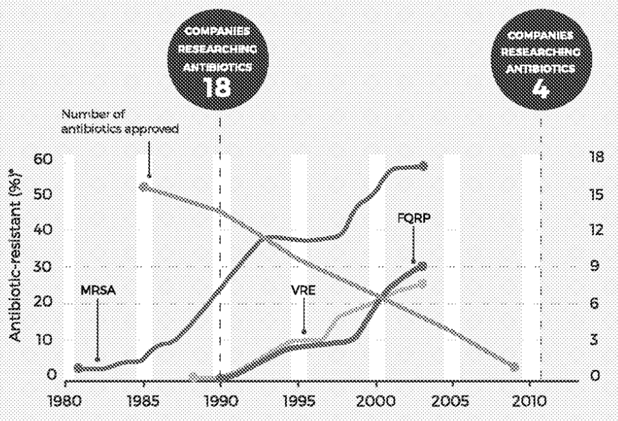
According to WHO, an estimated 1.7 billion people in 185 countries needed mass and/or individual treatment and care for neglected tropical diseases (NTDs) in 2014.[20] Despite NTDs accounting for approximately 12% of total disease burden, just 4% of therapeutic products registered between 2000 and 2011 were indicated for these diseases.[21] Rapid point-of-care diagnostics, particularly for use in resource-limited settings and in health emergencies, such as Ebola and Zika, are essential.[22] But diagnostics can be complex and costly to develop,[23] resulting in an inadequate number on the market.[24] And in spite of progress, paediatric formulations remain scarce for conditions that affect children.[25] The reasons behind the inadequate supply of paediatric formulations are complex and are also linked to a reluctance to conduct clinical trials with children.[26]

In spite of many notable advancements, numerous challenges remain. In some cases, progress has been uneven, leaving many people without access to the benefits of the advances made. The causes for this vary, but one can be attributed to inadequate investments in R&D for diseases for which the market does not provide sufficient financial return, as is the case for antimicrobial resistance (AMR). If not controlled or reversed, drug-resistant viruses, bacteria, parasites and fungi could, according to projections, cause 10 million deaths a year

Antimicrobial resistance (AMR) – a crisis in waiting

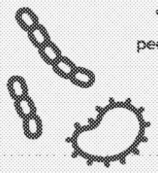
No more evident is the need for a collaborative global health response than with AMR, which threatens the foundation of modern health systems and can undermine efforts to achieve the SDGs.

As bacterial infections grow more resistant to antibiotics, companies are pulling out of antibiotics research and fewer new antibiotics are being approved.



*Proportion of clinical isolates that are resistant to antibiotic. MRSA, methicillin-resistant Staphylococcus aureus. VRE, vancomycin-resistant Enterococcus. FQRP, fluoroquinolone-resistant Pseudomonas aeruginosa.[1]

AMR estimated to kill more than **700,000** people globally per year today.[2]



If AMR is not addressed, **10 million** people are expected to die annually because of drug resistance by 2050.[2]

In the last **25 years** virtually no new antibiotics have been developed.[2]

The world can expect to lose about **100 trillion USD** worth of economic output by 2050 if antimicrobial drug resistance is not tackled.[3]

A continued rise in antimicrobial resistance would lead to a global reduction of **2% - 3.5%** in Gross Domestic Product (GDP) by 2050.[2]

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[1] Cooper. A. *et al* (2011) Fix the antibiotics pipeline. Available at: http://www.readcube.com/articles/10.1038/472032a

[2] O'Neill, J. (2014) Antimicrobial resistance: Tackling a crisis for the health and wealth of nations. The review on antimicrobial resistance. Available at: http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

[3] WHO (2016) What you need to know about antibiotic resistance. Available at: http://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

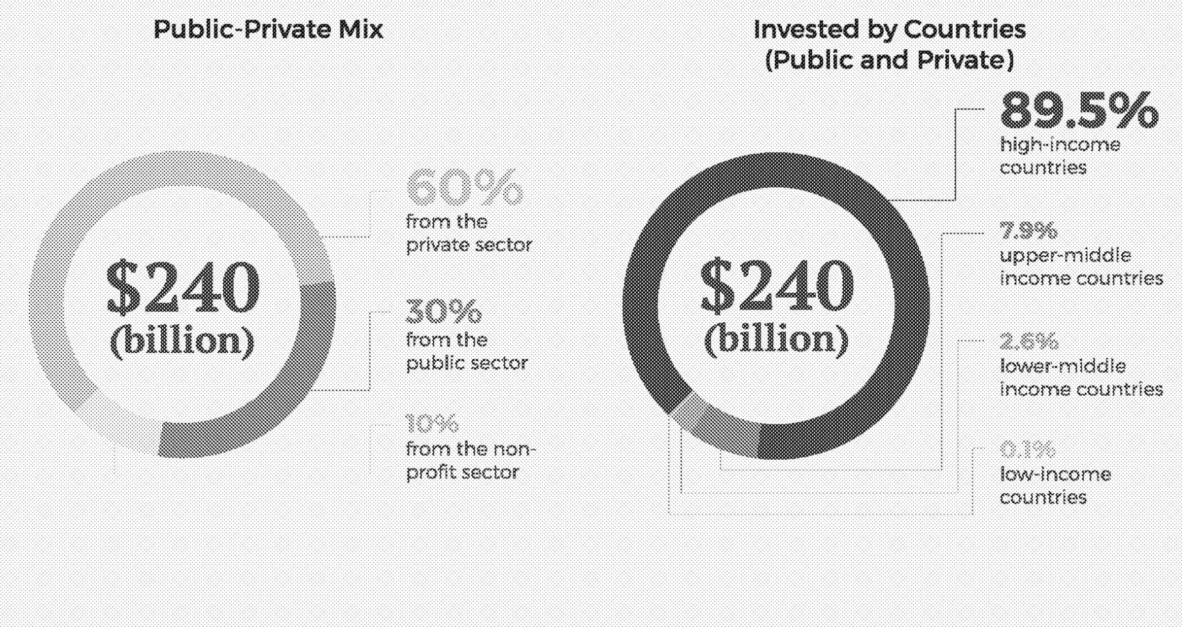
by 2050, and cost the global economy at least US$ 100 trillion, affecting wealthy and resource-constrained countries alike (see chart). Yet, aside from bedaquiline, a medicine approved in 2012 to treat multi-drug resistant tuberculosis (MDR-TB), only one novel class of antibiotics has been developed in the past 40 years. From a public health perspective, therefore, it is imperative to develop new antimicrobials and to control their use with the aim of preserving them, thereby breaking the resistance cycle. However, lower consumption signifies reduced sales, carving into any potential profit margins, such that few single players are willing to invest the financial, technical and human resources necessary to bring an antimicrobial medicine to market.

Coordinated and collaborative efforts of public-private partnerships and product development partnerships (PDPs) have been key to bringing together the resources and strengths of the private, philanthropic and public sectors to innovate and deliver several important health technologies.[27] International organizations, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), UNITAID and the United States President's Emergency Plan for AIDS Relief (PEPFAR), aggregate and distribute resources for tackling diseases, including malaria and tuberculosis, while the Gavi Alliance contributes to improving access to vaccines in poor countries. In the absence of a viable market, the existence of these mechanisms may help provide alternative incentives and financing for health technology innovation and access.[28] What some of these arrangements and mechanisms have in common is the concept of delinkage, which, for the purposes of this report, refers to separating the costs of R&D from the end prices of health technologies. Innovative mechanisms to address unmet needs have enabled policymakers to plan and budget R&D expenditure more rationally so as to use resources more efficiently and — most importantly — to invest according to public health priorities.[29]

Adequate investment in R&D by the public sector is crucial if governments are to fulfil their obligations with respect to the right to health. An analysis of spending on health technology R&D in wealthy countries found that 60% derived from the private sector and 40% from public and non-profit sources.[30] The percentages were reversed for R&D in diseases that heavily affect low- and middle-income countries, including HIV,[31] TB[32] and malaria.[33] For those conditions, the public sector provided approximately 60% of total R&D funding.

Innovation is vital to achieving the 2030 Agenda's goal of improving the health and well-being of all people at all ages and appears in a number of SDG targets. SDG 3 would require conducting more holistic situation assessments, prioritizing the most pressing public health needs by the funders of health R&D, financing equitably and sustainably and using public and private resources more prudently and strategically. Transparent, reliable and widely-available data is crucial to inform the policy-making process at various stages. This could include data on costs, pricing and patent information. It might also involve the creation or population of existing clinical trial

Investments in research and development (2009/2010)[1]



[1] Rounded estimates of total investment in health R&D in purchasing power parity-adjusted US$. See RØttingen, J., *et al.* (2013) Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?. The *Lancet*, 382(9900), pp.1286-1307.

data repositories, and easily accessible databases on patent and pricing by country and the costs of R&D. This information must be available for better governance and accountability and could help minimize redundancies and maximize returns on investments, ensuring innovation and access can take place that will benefit patients and public health objectives.

Cost is one of the key determinants of access, both in situations when patients pay out-of-pocket[34] and when governments are making choices about what to fund under national health and treatment programmes. According to WHO and the World Bank, 400 million people worldwide lack healthcare, including access to medicines, vaccines and diagnostics and medical devices.[35] Those who lack access are disproportionately poor, and three-quarters of them live in so called middle-income countries.[36] Individuals living on low incomes in many wealthy countries face challenges in accessing treatment for some infectious diseases, noncommunicable and rare diseases.[37] For example, a recent study found that the median nominal factory price of a 12-week course of sofosbuvir across 26 Organization for Economic Co-operation and Development (OECD) countries was US$ 42,017 and ranged from US$ 37,729 in Japan to US$ 64,680 in the United States. [38] These price discrepancies also reflect the capacity of countries to negotiate prices. Treatment for rare diseases can be exorbitantly costly. For instance, ivacaftor, an effective medicine for some people with cystic fibrosis, costs as much as US$ 294,000 per patient per year in wealthy countries (2011).[39]

Box 1: One South African patient's journey with extensively drug-resistant tuberculosis

South African Phumeza Tisile was diagnosed with TB in 2010. "First, I was diagnosed with 'normal TB,' then later I was told that I had multi-drug resistant TB, only to be told later again that I had extensively drug-resistant TB," explains Phumeza. The reason for the incorrect diagnosis was that the GeneXpert® machine used to diagnose multi-drug resistant and extensively drug-resistant TB was not available in South Africa at the time.

"Of course, the normal TB medication did not work," says Phumeza. "When I was told I had multi-drug resistant TB, I had to swallow around 20 tablets every day for more than three years. I took close to 20,000 tablets, of all sizes and colours, along with painful injections for the first six months."

According to her doctors, Phumeza needed the drug linezolid. The private sector price for each linezolid pill was South African Rand 676 (US$ 67 at the time). A quality-assured generic version was available through the Global Fund programme for US$ 7.90 per pill, but this version could not be used in South Africa as a patent was preventing generic competition. Finally, in 2013, Phumeza gained access to linezolid through the non-governmental organization Médecins Sans Frontières.

Fortunately for other extensively drug-resistant TB patients in South Africa today, the patent on the originator product has expired and a generic company has been registered in South Africa with others pending registration. The South African government now purchases linezolid on tender for the public sector at South African Rand 100 (US$ 6.86) per pill, which is close to the lowest global price of US$ 5.35 per tablet.

"The side effects of MDR-TB drugs are a nightmare," recalls Phumeza, "skin problems and vomiting every day. I even had surgery and became deaf from the kanamycin injection."

Despite the side effects, Phumeza says she pulled through and stayed alive by daring herself to "not end up in a body bag" like others she had seen at the hospital. "Linezolid was the key player in all of this," she notes. "Without it, I am not sure if I would still be here. At the time, not many patients were lucky enough to get linezolid because it was too expensive."

In 2015, Phumeza received cochlear implants, paid for through a crowd funding website and medical insurance, which restored her hearing. "But now tell me this," asks Phumeza, "how is someone from South Africa able to pay 500,000 South African Rand [US$ 37,650 according to average 2015 exchange rates] to afford cochlear implants?"

Phumeza's story highlights the importance of patients having access not just to medicines, but to all health technologies, including vaccines, diagnostics and medical devices, in order to prevent and treat illness.

1.1 Multiple barriers to access

Many reasons exist why people do not get the healthcare they need, ranging from: under-resourced health systems, a lack of sufficiently qualified and skilled healthcare workers, inequalities between and within countries, exclusion, stigma, discrimination and exclusive marketing rights, to name a few. WHO has recognized that the myriad of problems affecting health technology innovation and access (including unaffordability, poor quality, inappropriate use, procurement, supply chain and regulatory obstacles for both originator and generic products alike, etc.) reflect weaknesses of public health systems overall, especially in poor countries.[40]

Adequate financing of health technology R&D is needed and steps must be taken — by governments in particular — to guarantee investments that lead to equitable access, especially for poor and vulnerable populations. Robust information systems are fundamental for ensuring consistent pricing, payment and reliable supplies (for example, a well-managed supply chain can help avoid stock-outs and delays). At the point of care, service delivery must also be effective. Well-trained personnel at each stage of service delivery is critical to ensure that the right populations are identified for preventive interventions; that diagnostics are used effectively; that medicines are properly prescribed and dispensed; and that advice on the use of health technologies is conveyed in a way which encourages adherence and proper use.

WHO recommends, among other things, that closer attention is paid to the bottlenecks that prevent equitable access to medicines across populations. There must be fair and transparent selection for inclusion on national essential medicines lists, greater use of innovative pricing and financing strategies, more efficient supply models and more effective incentives for the appropriate use of medicines. While most essential medicines (as listed by WHO, see below box) are off patent, millions of people still do not have access to them.[41] Regulatory inefficiencies, poor health education, unavailability of health insurance and insufficient financial protection for those who have to pay for some or all of their treatment are major barriers to access.[42] Others note that fees, profits, taxes and tariffs along the supply chain can inflate prices significantly, but governments have been hard-pressed to track and control these increases.[43]

Box 2: WHO Essential Medicines List

The first WHO Essential Medicines List (EML) was published in 1977 in response to World Health Assembly Resolution WHA28.66 calling on WHO to assist Member States to select and procure essential medicines of good quality and at a reasonable cost. Over the past 39 years, 18 revisions of the list have been published. The selection criteria has evolved from an experience-based to an evidence-based approach, incorporating public health relevance, efficacy, safety and cost-effectiveness.[44]

The EML provides a model for at least 156 national medicines lists and is a key component of national medicine policies and medicine access initiatives. Divergence between the EML and national lists are caused, inter alia, by differences in local and regional morbidity patterns, time lags associated with new additions and country-level cost-effectiveness assessments. While the majority of medicines on previous revisions of the EML have historically been off-patent, the inclusion of new high-priced, patented treatments for hepatitis C, cancers and MDR-TB on the 2015 EML was an unprecedented development.[45]

The High-Level Panel is fully aware and acknowledges the critical importance of addressing the multiple determinants of access as well as the important work being undertaken by organizations and groups to surmount the enormous hurdles in these areas. It is critical that governments, international agencies, civil society and other relevant stakeholders work together to address the multiple determinants of access within health systems. While fully appreciating the broader context and determinants of health technology access, the High-Level Panel's recommendations focus on its mandate to address a specific and important aspect of health technology innovation and access: the policy incoherencies between trade and intellectual property rules, public health objectives and international human rights. The High-Level Panel has focused on its mandate while noting that these other issues are also of critical importance in determining access to health technologies.

1.2 Policy incoherencies

Policies that have a bearing on access to health technologies that are associated with trade, intellectual property, health and human rights were developed with different objectives and at different periods in history. Each is governed by its own legal and regulatory regime and each imposes obligations that may not align with the others. Trade and intellectual property rules were not developed with the goal of protecting the right to health, just as human rights doctrine does not primarily concern itself with promoting trade or reducing tariffs. Intellectual property regimes seek to balance the rights of inventors with the wider interests and needs of society.[46] Policy incoherencies arise when legitimate economic, social and political interests and priorities are misaligned or in conflict with the right to health. State obligations include duties not only to respect, but to protect and fulfil the right to health. This requires taking proactive measures to promote public health.

Another key aspect of incoherence lies in the misalignment between market-based models that incentivize innovation and the need to obtain treatment for patients. State obligations include duties not only to respect, but to protect and fulfil the right to health; which requires States to take proactive measures to promote public health.[47] As reaffirmed by a recent resolution of the Human Rights Council, ensuring access to medicines, and particularly to essential medicines, is a fundamental element of these obligations.[48] Yet, insufficient investment is being made in R&D for diseases that predominantly affect the poor. Furthermore, prices charged by some right holders place severe burdens on health systems and individual patients, in wealthy and resource-constrained countries alike.

The role of public funding of health technology R&D can also fuel incoherence, for example when public funding is used to subsidize private sector research, only for the fruits of such research to be priced out of reach for both public and private sector consumers.

Box 3: The right to health and the responsibilities of governments and other parties

The right to the enjoyment of the highest attainable standard of physical and mental health was first articulated in the WHO Constitution of 1948, whose preamble described it as "one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[49] The right to health is also enshrined within Article 25 of the 1948 Universal Declaration of Human Rights, Article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) and various other international treaties, declarations and national laws, including at least 115 national constitutions. States are obliged to respect, protect and fulfil the right to health, which includes a duty to ensure that medicines are available, accessible, culturally acceptable and of good quality.[50] The 2006 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, reiterated the obligation of states to fulfil the human right to medicines and to make full use of TRIPS flexibilities for this purpose.[51]

The 2009 Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health further explored the impact of TRIPS and TRIPS-plus provisions on the right to health and in particular on access to medicines. While calling on all countries to incorporate and make full use of TRIPS flexibilities, the Special Rapporteur further called on developing and least developed countries not to introduce TRIPS-plus provisions in their national laws and on developed countries not to include such provisions in free trade agreements.[52]

Human rights law recognizes that the full achievement of all rights requires resources. There is a legal obligation of progressive realization: each state party must "take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant." [53]

The right to health also imposes a duty on states to protect the right against abuses by third parties.[54] In its "Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights," the United Nations Sub-Commission on the Promotion and Protection of Human Rights recognized that although states bear the primary responsibility to promote, respect and protect human rights, "transnational corporations and other business enterprises…are also responsible for promoting and securing…human rights". [55]

While the Universal Declaration of Human Rights and the ICESCR protect the right to health and the right to enjoy the benefits of science, they also guarantee the rights of scientists, artists and authors to protect their work's integrity and reap its financial benefits.[56] However, it is worth emphasizing that the United Nations Committee on Economic, Social and Cultural Rights (CESCR), an independent body of experts that monitors ICESCR implementation, clarified that natural persons, not corporations, have human rights to these protections. This protection, the Committee wrote, "is a human right, which derives from the inherent dignity and worth of all persons," a fact that "distinguishes human rights from most legal entitlements recognized in intellectual property systems." [57]

1.2.1 The TRIPS Agreement and the right to health

Since the emergence of formal patent statutes over 500 years ago, governments have granted temporary monopolies with conditions attached, such as, for instance, requiring the right holder to train local artisans in the craft and technology that produced the product.[58] The rules that spur innovations and govern their protection and diffusion evolve in accordance with the exigencies of trade. It remains important, however, that national and multilateral policies balance objectives: trade promotion and liberalization versus the protection of domestic industries and citizens. The first formal multilateral patent treaty, the 1883 Paris Convention for the Protection of Industrial Property, imposed a set of global norms, but it also left signatories significant room to use intellectual property to pursue national goals. States retained the discretion to determine the duration of a patent under national law and to exclude certain fields of technology from patentability. The Convention also provided for the revocation of patents and the issuance of compulsory licences to remedy abuses by right holders.[59]

In 1986, when trade negotiations leading to the establishment of the WTO commenced, 50 countries did not provide patent protection on pharmaceutical products.[60] This remained essentially unchanged for the next decade, although some Andean countries began adopting pharmaceutical patent protections in the 1990s. In 1995, with the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the aegis of the WTO, a new and unprecedented era of global intellectual property norms began. The TRIPS Agreement was a watershed in the evolution of intellectual property protection. Its provisions required WTO Members subject to the transition periods then available for developing countries (and still available to LDCs) to provide a 20-year period of patent protection on health technologies. WTO Members were required to implement the TRIPS Agreement as a condition of their membership, which most governments saw as crucial in a global economy.

For many countries and public health proponents, provisions embodied in the TRIPS Agreement presented a policy dilemma. On the one hand, governments embraced the agreement for the economic benefits of increased trade. On the other, the obligation to grant patents on medicines and other health technologies would affect the availability and affordability of health technologies. This obligation had a clear potential to strain national budgets and to place health technologies out of the reach of those in need. Meanwhile, human rights law—both binding international treaties and national statutes—required governments to progressively realize the highest attainable standard of health.[61]

To address these tensions, negotiators included safeguards in the TRIPS Agreement that could be used to promote the right to health. Article 7, for instance, provides that intellectual property rights should advance technological innovation and the dissemination of technology "to the mutual advantage of producers and users…in a manner conducive to social and economic welfare, and to a balance of rights and obligations." Article 8 (1) provides that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement."

The TRIPS Agreement also included 'flexibilities' that enable signatories to tailor and employ national intellectual property law, competition law, medical regulations and procurement laws to fulfil their human rights and public health obligations. Among the most discussed TRIPS flexibilities are compulsory licences, wherein a government imposes the terms under which a patented product can be used or produced in generic versions without the consent of the patent holder.[62]

Box 4: Public health-related TRIPS flexibilities: A snapshot [63]

Flexibility	TRIPS Article	Explanation
Parallel imports	6	Goods legitimately placed on another market may be imported from another market without permission of the right holder because of the exhaustion of the patent holder's exclusive marketing rights.
Patentability criteria	27	WTO Members may develop their own definitions of 'novelty,' 'inventive step' and 'industrial application.' They can also refuse to grant patents for certain subject matter, e.g. plants and animals.
General exceptions	30	WTO Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.
Compulsory licensing	31	A non-voluntary licence may be granted by a duly authorized administrative, quasi-judicial or judicial body to a third party to use a patented invention without the consent of the patent holder, subject to the payment of adequate remuneration in the circumstances of each case.
Government use	31	A government authority may decide to use a patent without the consent of the patent holder for public, non-commercial purposes, subject to the payment of adequate remuneration in the circumstances of each case.
Competition-related provisions	8, 31(k), 40	Members may adopt appropriate measures to prevent or remedy anti-competitive practices relating to intellectual property. These include compulsory licences issued on the basis of anti-competitive conduct and control of anti-competitive licensing.
Transition periods	65, 66	LDCs are not required to provide patent or data protection in general until 1 July 2021 and on pharmaceutical products are not required to grant or enforce patents or data protection until 1 January 2033, or a subsequent date as agreed by WTO Members.

A few years after the TRIPS Agreement came into force, the context of the burgeoning AIDS pandemic at that time made it clear that WTO Members had yet to reach consensus on how to interpret and apply the flexibilities within the agreement.[64] Many WTO Members sought consensus on interpretation of the TRIPS Agreement. An accord was finally reached and is embodied in the Doha Declaration on the TRIPS Agreement and Public Health (2001). The Doha Declaration stresses that TRIPS "can and should be interpreted and implemented" to support the "right to protect public health [and] promote access to medicines for all," including the sovereign determination of the grounds under which a compulsory licence may be issued.[65]

Box 5: The Doha Declaration on the TRIPS Agreement and Public Health

Notwithstanding the public health flexibilities included in the TRIPS Agreement, in the late 1990s, in practice, the right to make use of these flexibilities by governments of developing countries was challenged by the pharmaceutical industry and by governments of a number of high-income countries. In this context, WTO Members sought to reach consensus on the relationship between the TRIPS Agreement and public health.

In April 2001, the TRIPS Council held a Special Session to discuss the right of WTO Members to use TRIPS flexibilities. After protracted negotiations, the Doha Declaration was adopted on 14 November 2001. The Doha Declaration affirms the rights of WTO Members to use flexibilities in the TRIPS Agreement to promote public health objectives. The Doha Declaration states:

1. *We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.*

2. *We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.*

3. *We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.*

4. *We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS*

Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. *Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:*
   a. *In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*
   b. *Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.*
   c. *Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*
   d. *The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without* challenge, subject to the most-favoured-nation and national *treatment provisions of Articles 3 and 4."*
6. *We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.*
7. *We reaffirm the commitment of developed country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed country members pursuant to Article 66.2. We also agree that the least developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016, without prejudice to the right of least developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.*

Since the TRIPS Agreement came into effect, bilateral and regional free trade agreements (FTAs) concluded by several governments have progressively expanded and deepened patent and test data protections on health technologies. Such provisions further exacerbate policy incoherence by narrowing the options provided by the TRIPS Agreement and the Doha Declaration for governments to ensure that intellectual property protection and enforcement does not undermine their human rights obligations and public health priorities. A number of provisions found in bilateral and regional FTAs exceed the minimum standards for intellectual property protection and enforcement required by the TRIPS Agreement. These provisions may impede access to health technologies, including those requiring governments to ease standards of patentability[66], drug regulatory authorities to link marketing approval to the absence of any claimed patent[67] and the requiring of test data exclusivity instead of test data protection, to list a few.[68]

The recent Trans-Pacific Partnership Agreement (TPP), which is yet to come into force, is emblematic of the new generation of bilateral and multilateral trade and investment agreements which include 'TRIPS-plus' provisions that progressively ratchet up intellectual property protection and enforcement.[69] This new generation of trade and investment agreement often includes dispute settlement mechanisms that establish arbitration processes outside of national courts and allow private firms to challenge national laws for depriving them of future profits. Other provisions restrict government ability to regulate pharmaceutical prices and reimbursement mechanisms. Such provisions significantly reduce the scope of measures that national governments can use to pursue public health priorities and fulfil the right to health. Ensuring that future trade agreements do not interfere with policies that guarantee the right to health for all is essential for resolving the incoherence between trade agreements and the human right to health.[70]

The High-Level Panel noted that a number of contributions pointed to a progressive de-prioritization and erosion of human rights in the implementation of intellectual property law and policy, both under TRIPS and as a result of recent trade agreements. A number of calls, including to the High-Level Panel, have been made for a new United Nations instrument to uphold universal human rights in laws, policies and actions that affect health technology innovation and access. The High-Level Panel did not reach consensus on this proposal. While recognizing the importance of these calls, the High-Level Panel concluded that human rights and other obligations as they relate to access to essential medicines already exist and are embedded in United Nations instruments, guidance and decisions of human rights bodies and in a number of national and regional legal instruments. If given proper effect and properly observed, the provisions of TRIPS and the Doha Declaration would give rise to the necessary protections and required balances to protect the human right to health in trade and intellectual property matters. To revise or update these existing rights would be to concede ground to any argument of their derogability. Therefore, and in light of the urgency of addressing the health technology innovation and access challenges in line with its mandate, members of the High-Level Panel agreed in its recommendations to reinforce those rights in current existence and underline the need for greater attention, monitoring and enforcement to ensure that these rights are not undermined and are actively pursued.

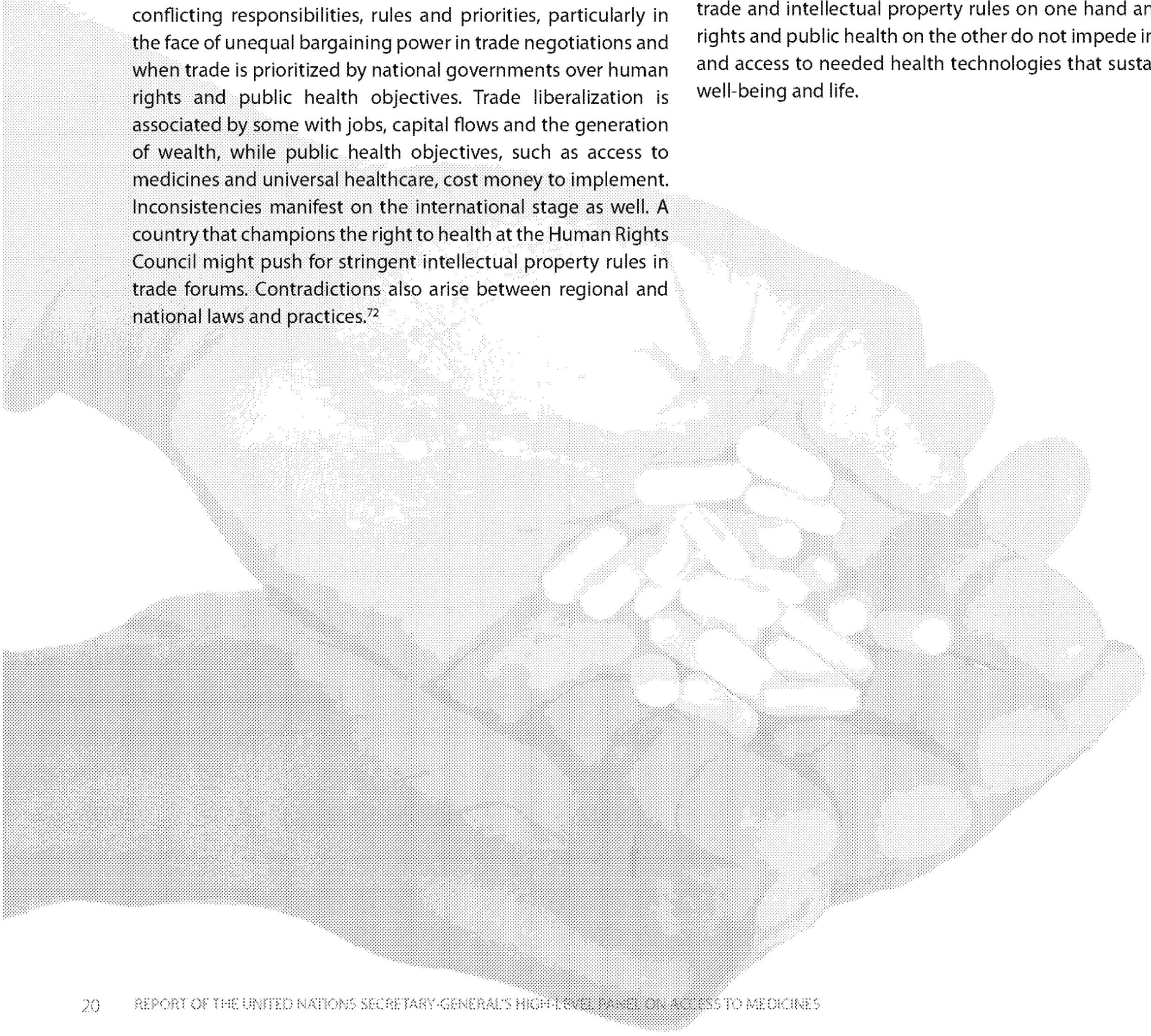
1.2.2 Incoherencies and asymmetries of power

The Doha Declaration confirms that the TRIPS flexibilities are not exceptions, but rather, a fundamental part of the TRIPS machinery. Yet, numerous incoherencies and troubling practices have obstructed sovereign freedom of governments in using flexibilities to promote public health.[71] One critical incoherence is the uneven application of health and trade policy within and among WTO Members. The signatories to TRIPS have not pursued implementation of the flexibilities that protect the health of their populations with the same vigour as they have introduced and enforced the intellectual property protections. The right to health and the right to benefit from scientific progress were articulated in the Universal Declaration of Human Rights. But, while inalienable and universal, their enforcement and accountability mechanisms pale in comparison to those found in intellectual property law.

Governments, especially those without economic clout, cannot confront this unevenness of enforcement without singleness of purpose. However, governments face competing and often conflicting responsibilities, rules and priorities, particularly in the face of unequal bargaining power in trade negotiations and when trade is prioritized by national governments over human rights and public health objectives. Trade liberalization is associated by some with jobs, capital flows and the generation of wealth, while public health objectives, such as access to medicines and universal healthcare, cost money to implement. Inconsistencies manifest on the international stage as well. A country that champions the right to health at the Human Rights Council might push for stringent intellectual property rules in trade forums. Contradictions also arise between regional and national laws and practices.[72]

Even when there is no incoherence in policy and law, inequality of bargaining power among domestic government departments and the asymmetry of power between well-resourced and poorer countries and between corporations and citizens can facilitate interpretations of the law that fuel incoherence.[73] Governments and corporations sometimes threaten political or economic retaliation as a means of illegitimately pressuring others into forgoing their TRIPS flexibilities.[74] Such actions are against the letter and spirit of the TRIPS Agreement and the Doha Declaration. They also undermine efforts by governments to meet their human rights obligations.

Policy incoherence is not always a matter of law. It is also a matter of interpretation and application, shaped by priorities and politics. Human rights are fundamental, universal entitlements that people inherently acquire by virtue of their birth. In comparison, intellectual property rights are "one policy tool among many for encouraging innovation and technological research and development." [75] Intellectual property rights are temporary, revocable, transferable privileges granted by states and can be suspended or revoked under certain conditions laid out in the TRIPS Agreement when it is in the interest of the state or society. The international community must unite to build sustainable solutions so that policy incoherencies between trade and intellectual property rules on one hand and human rights and public health on the other do not impede innovation and access to needed health technologies that sustain health, well-being and life.



2. INTELLECTUAL PROPERTY LAWS AND ACCESS TO HEALTH TECHNOLOGIES

Intellectual property refers generally to legal rights resulting from intellectual activity in the fields of industry, science, or art. Through patents, which are one form of intellectual property provided for inventions, countries grant the holders of intellectual property time-limited control on the use of this property. Patents are sets of exclusive rights, granted by a state authority, or a patent organization recognized by the state to inventors or assignees, which could be physical persons, or legal entities, including corporations. Patents are granted for a limited period of time in exchange for the detailed public disclosure of the invention.[76]

It is these patents, along with other forms of intellectual property rights and various types of direct or indirect government or public support, that have enabled right holders to generate the revenues that have contributed to the R&D of medicines, vaccines and diagnostics over the last half century or so that have benefited health and human development.[77] While some assert that intellectual property policy is working as intended,[78] others note that patent protection and enforcement should better balance the interests of the holder of the property rights and the interests of society,[79] and that the needs of the poorest still are not met. When profit is the primary engine for innovation, public health needs can be neglected and the right to health impeded. How can current laws, policies and practices work better to match the objectives of intellectual property policies with those of human rights obligations and public health priorities? To address the misalignment between public health objectives and trade and intellectual property protection, it will be necessary to identify the models and mechanisms that can remedy shortcomings in the existing intellectual property regime.[80]

As noted earlier, governments retained significant flexibility to adapt their patent laws to advance public health objectives before the TRIPS Agreement. For instance, Canada made regular use of compulsory licensing to promote local production of pharmaceuticals, resulting in some of the lowest consumer prices for medicines in the industrialized world. Between 1969 and 1992, there were 1,030 applications to import or manufacture medicines under these licences, of which 613 were granted by authorities.[81] When the Republic of Korea adopted a Patent Act in 1961, it excluded foodstuffs, chemicals and pharmaceuticals from patentability and only allowed for 12 years of patent protection on other fields of technology.[82] India is the most often cited example of how a government used their freedom to adapt domestic intellectual property laws to meet national objectives. Concerned in part by high prices, India passed a Patent Act in 1970 that excluded pharmaceutical products from patent protection. This reduced the number of patents by as much as 75%, according to some estimates, and paved the way for India's thriving generic medicines industry.[83] These are just a few mechanisms that have been used by governments out of a range of voluntary and non-voluntary mechanisms available to increase access to health technologies and promote the right to health.

While the price of health technologies is influenced by a variety of factors, including the size of the potential market and the results of negotiations with public and private insurers, intellectual property concerns also play a central role. Article 7 of the TRIPS Agreement claims that intellectual property aims to foster innovation and thereby improve societal well-being, but paradoxically, it achieves this in the short-term by creating a monopoly whereby patent holders bear significant power over end prices, rather than the usual open market. For some countries, prices of innovative health technologies have increased more quickly in recent years than the average consumer price index.[84] In some cases, the application of patent protections required by the TRIPS Agreement can conflict with the right to health in rich and poor countries alike, thus resulting in policy incoherencies and tensions. IP rights confer patent monopolies on the right holder, who in turn often charges whatever price the market will bear.

For example, over the past decades, revolutionary treatments for cancer have been developed. But, these life-saving treatments, while under patent protection, can be financially unsustainable, particularly when the costs have to be borne by the patients themselves. Even in countries with public and/or private healthcare systems, patients are frequently saddled with unmanageable out-of-pocket expenses.[85] In the United States, prices of cancer medicines have almost doubled from a decade ago, averaging from US$ 5,000-10,000 per month. Of the 12 medicines approved by the United States Food and Drug Administration (FDA) for various cancer indications in 2012, 11 were priced above US$ 100,000 per year.[86] In rich and poor countries with public health systems, government expenditures on health technologies is a significant proportion of overall government and health department expenditure, diverting resources away from other essential health services.[87]

Box 6: The impact of the high cost of health technologies

"Sofosbuvir is an important breakthrough in the treatment of patients with chronic hepatitis C. The problem is that a one-time treatment costs between 48,000 and 96,000 Euros. The Netherlands has an estimated 20,000 patients with this disease. The supplier defends this price in part by pointing to the great value to the patient and to those affected by the patient's illness. But such costs make healthcare unaffordable. If the Netherlands continues in this way, it will become nearly impossible to reimburse patients for these medications."

Contribution from the Ministry of Foreign Affairs, the Kingdom of the Netherlands, 27 February 2016

2.1 Voluntary licences

Voluntary licences are private contracts entered into between right holders and third parties to facilitate the market entry of more affordable treatments.[88] Voluntary licences enable the right holder to maintain a degree of market control by selecting the countries where voluntary licences are negotiated and concluded. The terms and conditions of voluntary licences, such as the number of patients that can be treated, the types of suppliers from whom active pharmaceutical ingredients must be sourced and the amount of royalty paid to the right holder, can vary widely. The level of transparency in licensing agreements executed by the UNITAID-backed Medicines Patent Pool (MPP), in which all licences are publicly available, is laudable and rare. Voluntary licences can be an important enabler of treatment access. For example, in less than four years, licences negotiated through the MPP are estimated to have generated US$ 120 million in savings globally and supplied seven million patient-years of WHO-recommended ARV medicines.[89]

To date, voluntary licensing mechanisms established to support patent pooling have typically focused their efforts on health technologies for specific diseases. The decision of the MPP, therefore, to broaden its scope beyond HIV to TB and hepatitis C in late 2015 is an important development.[90]

Geographical limitations are another traditional downside of voluntary licences. Irrespective of disease burdens and in some cases high levels of income inequality, developed countries, as well certain developing countries with comparatively high levels of per capita income are usually excluded from the scope of licences, as right holders reserve the right to identify countries where they intend to sell the product directly or through other agreements.[91] An example of this is the voluntary licences concluded between Gilead and various generic companies covering 101 countries for the hepatitis C medicine, sofosbuvir. The high prices at which the products are sold to governments outside of its geographical scope can create tensions and raise serious concerns around access.[92]

2.2 TRIPS flexibilities

As mentioned above, even though the TRIPS Agreement ushered in a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important public health flexibilities that can be used to adapt their intellectual property law, policies and practices to meet human rights and public health objectives. These include the ability to determine patentability criteria, issue compulsory licences, authorize parallel importation, apply general exceptions and employ competition laws to limit and remedy the abuse of intellectual property rights in domestic legislation. Patentability criteria, compulsory licences and competition law will be discussed below.

2.2.1 Patentability criteria

The TRIPS Agreement does not define patentability requirements per se, except to say that an invention must be novel, involve an inventive or non-obvious step and be industrially applicable or useful.[93] This leaves considerable discretion to governments to define and apply these criteria within national legislation.[94] At one end of the spectrum are national authorities who either do not undertake substantive patent examination or who interpret the criteria broadly, granting secondary patents that in effect extend the original patent based on varying methods of use, formulations, dosages and forms of constituent chemicals.[95] At the other end of the spectrum are national authorities with provisions stating that a mere discovery of a new form of a known substance that does not improve efficacy is not patentable.[96] Similar to the use of flexibilities in general countries applying a public health-based interpretation of patentability criteria have faced pressure against such an interpretation and application in their national laws.[97]

In some instances, secondary patents are granted for minor but important changes to an existing product. Secondary patents can, however, prolong exclusivity (commonly known as 'evergreening'). In doing so, entrance of generic or competing products can be curtailed and prices remain high, thereby limiting patient access to health technologies.[98] Furthermore, secondary patents can create legal uncertainty around the patent status of a health technology, which in turn discourages entities from procuring generic versions of products for fear of patent infringement.[99] In some instances, however, changes to existing medicines may add important therapeutic value by, for example, helping patients to tolerate the medicine better. This, in turn could promote competition with the original medicine. Secondary patents may also be important for the development of safer, less toxic and more effective health technologies.[100]

Since the TRIPS Agreement entered into force, patents have been increasingly seen as a potential source of income for health researchers with the result that more complex patenting strategies are being adopted. Patent right holders and originators can file multiple applications for the same invention that create a set of overlapping patent rights that may be difficult to negotiate (known as 'patent thickets'). The result of these practices is that a party that seeks to commercialize new technology may need to obtain permission from multiple patentees. A 2011 patent landscape analysis found that the antiretroviral medicine ritonavir, for instance, was protected by 805 patent families held by the originator and other research-based companies.[101]

Empirical studies of patent thickets show varied results, highlighting potential impacts which range from: 1) discouraging others from undertaking research on competing products; 2) high licensing costs; 3) refusal of the patent holder to grant a licence to one or more of the patented technologies; 4) competing products potentially infringing on a number of patents and thus requiring multiple royalty payments (known as 'royalty stacking'); and 5) difficulties associated with inventing around a group of patents.[102] In one study of biomedical researchers, three quarters of the researchers reported encountering difficulties in accessing patented technologies, which resulted in half of them changing their research plans and 28% abandoning their plans altogether. Patent thickets also affect commercial decisions by would-be makers, sellers and importers of medicines and health technologies.[103] Governments can adopt legislation to limit excessive patenting that stifles health technology R&D and access. The application of public health-sensitive guidelines in country patent offices may be an important policy tool to improve health technology access.[104]

2.2.2 Compulsory licences

The TRIPS Agreement preserves the right of WTO Members to grant compulsory licenses on a number of grounds, including instances in which a license is in the public interest, there are abuses of rights or anti-competitive conduct, or for public non-commercial use, to name a few. Compulsory licences are an important policy tool for government authorities to promote access to health technologies. With a compulsory licence, a government imposes the terms under which a licence on a patented product may be used in that country by a third party without the consent of the patent holder. While the state denies the patent-holder a monopoly, it does not deny them remuneration—the beneficiary of the licence pays a royalty. The right holder retains its exclusive rights, except with regard to the compulsory licensee. The Doha Declaration dispelled the myth that compulsory licences should be limited to emergency situations by confirming that WTO Members were free to determine the grounds under which compulsory licences could be issued.

The principle of compulsory licensing has been an important part of patent law for centuries,[105] and the licences have been used by governments in all countries to serve the interests of society or the state, subject to the payment of a royalty to the right holder.[106] Some have expressed concerns that the prospect of compulsory licences drives off investment in countries that issue them[107] and there is apprehension that these governments could be subjected to retaliation. The threat of compulsory licences has been used by governments to obtain price reductions from patent holders, who generally found the lower negotiated prices preferable to receiving royalties.[108] In 2007, after protracted negotiations, the Brazilian government issued a compulsory licence for efavirenz, an important antiretroviral medicine then used by one-third of Brazilians use on treatment through the national programme. After the licence was issued, the price dropped from US$ 1.60 per dose to US$ 0.45 per dose for the imported generic version of the medicine.[109]

While most governments have compulsory licensing provisions in their patent legislation, the effectiveness of such laws is mixed. The High-Level Panel received a number of contributions making the case for international, regional and national mechanisms to enable more expedient and user-friendly processes for granting compulsory licenses. In particular, the High-Level Panel engaged in a robust debate as to whether governments should, in the interests of meeting human rights and public health objectives, be encouraged to implement a system of compulsory licensing in national legislation that is effectively automatic by way of its predictability and implementation, provided the requirements in Article 31 of the TRIPS Agreement are met. While a majority of Panel Members were in favour of such an approach, a sizable minority of Panel Members were not, because of concerns over the potential incompatibility of such measures with the TRIPS Agreement and the unintended consequences that may result from such an approach. The High-Level Panel therefore did not reach consensus on this particular issue. The High-Level Panel nonetheless urges that national laws should be drafted in a way that facilitates the prompt and expedient use of a compulsory licence or government use for non-commercial purposes of a patent, including criteria to determine the remuneration for the right holder. As the Doha Declaration notes, governments should retain the freedom to determine the grounds under which compulsory licences are issued.

The TRIPS Agreement requires that health technologies produced under compulsory licence be predominantly for domestic use. This poses little problem for countries with significant biomedical manufacturing capacity. However, for countries with no or insufficient health technology manufacturing capacity, this can pose a significant challenge. The "Paragraph 6 decision," was a temporary waiver agreed by WTO Members on 30 August 2003 meant to address this problem by removing the limitation to predominantly supply the local market. Two years later, on 6 December 2005, WTO Members agreed to submit the temporary waiver of 2003 as a Protocol for the first, and so far only, amendment of the TRIPS Agreement, subject to the acceptance of two-thirds of WTO Members.[110]

There are differing opinions as to why the "Paragraph 6 decision" has only been used once in 13 years. Some note that multilateral health financing has removed the need for resource-constrained countries to use it. Others argue that it is too complex to be used. The only time the mechanism was used, it proved to be complex and cumbersome[111] and serious questions remain as to its effectiveness.[112] More than 10 years after WTO Members agreed to transform the temporary waiver into an amendment of the TRIPS Agreement, the amendment is yet to be accepted by two-thirds of WTO Members.[113] At a time of increased political commitment to enhancing local pharmaceutical production in developing countries,[114] attention should be paid to incorporating efficient, easy to use compulsory licensing provisions into domestic legislation.

2.2.3 Competition law

Complementary tools to intellectual property laws, such as competition law, provide an important market-stabilizing effect on anti-competitive behaviour. Examples of anti-competitive practices in the health technologies sector include bid rigging, price fixing, exclusionary supply arrangements and anti-competitive mergers and acquisitions. Relating to intellectual property, anti-competitive practices might include restrictive licensing conditions, abusive patenting (e.g. to block generic entry) and excessive pricing.

Article 8(2) of the TRIPS Agreement[115] provides an insufficiently used opportunity for governments to prevent abuse of intellectual property rights by right holders and achieve price reductions for health technologies depending on the provisions of local competition laws. One such avenue is competition law and policy, which can be used to balance proprietary interests with economic and social interests to advance public welfare.[116]

Competition policy has been used to remedy anti-competitive conduct in the biomedical industry and to promote treatment access in many countries.[117] Various organizations have published guidance on competition law and offer support to WTO Members who may wish to regulate anti-competitive conduct in the health sector.[118] Competition policies are important levers that governments can employ to ensure that health technology markets operate competitively and that the public benefits from low prices and innovation. Should governments pay closer attention to competition law, it could serve as an important policy tool for increasing access to health technologies.

2.3 National coherence

Incorporating public health-related TRIPS flexibilities into national intellectual property law typically cuts across many government departments and ministries—trade and industry, economic development, science and technology, health, justice, foreign affairs, national planning and finance, to name the most obvious ones. Ministries in most national cabinets operate in an asymmetrical power structure and do not necessarily coordinate their objectives and actions with each other, thus fuelling policy incoherence at the national level. Special measures are needed to promote national coherence so that public and private interests are better balanced.[119] Tensions between ministries responsible for the promotion of trade and the protection and enforcement of intellectual property on the one hand and those responsible for public health should not result in the prioritization of trade over health. The very nature of fundamental human rights requires that they outweigh private interests under national law.

The flexibilities available in the TRIPS Agreement provide WTO Members with significant latitude to adapt and enforce their laws and policies to advance their national interests. Country-level, inter-sectoral coordination could be an important catalyst to supporting governments to translate policy space in TRIPS into coherent and comprehensive national laws. United Nations agencies and multilateral organizations should be supporting governments in the drafting of public health-sensitive national laws and policies, providing technical and advocacy support for using TRIPS flexibilities and helping governments negotiate trade agreements that incorporate an evaluation of public health and human rights impacts during and after negotiations, not according to their mandates, but in response to the public health needs of countries.

2.4 Limitations to the use of TRIPS flexibilities

The ability of United Nations Member States to achieve the Sustainable Development Goals and targets will depend on well-functioning national policies, including those relevant to health technology innovation and access. In particular, access to the fruits of innovation, including access to health technologies, requires that both the exclusive rights granted to innovators and the limitations and exceptions to those rights provided under national and international law are fully recognized and respected. Maintaining this balance is essential to realization of the public welfare and development objectives of the patent system and the TRIPS Agreement.

However, many governments have not used the flexibilities in the TRIPS Agreement. The reasons for this vary. In some cases, governments may not see the need to use them because national treatment programmes are presently being sustained by health financing mechanisms, such as the Global Fund and PEPFAR.[120] In other countries, where multilateral health financing is not available, there may be political will but capacity constraints may impede their effective use. Intellectual property laws are complex; technical assistance tailored to specific country contexts and needs while drawing on international experiences and good practices around improved coordination between different ministries could strengthen the negotiating ability of countries to ensure national and public health objectives are achieved.

Box 7: Obstacles to the use of TRIPS flexibilities

The Doha Declaration reaffirmed the rights of WTO Members to utilize flexibilities available under the TRIPS Agreement for the purpose of promoting the right to health and public health objectives. Despite these pronouncements, the sovereign right to issue compulsory licenses provided for by TRIPS has been stymied by threats of retaliation from governments and corporations against countries who have followed the prescribed process set out in TRIPS. The ensuing cloud of controversy, intimidation and legal incertitude associated with compulsory licenses have weakened the bargaining position of many WTO Members. It has also impeded the possibility of creative arrangements between governments and corporations with respect to strategies for the production and distribution of health technologies.

One such example is Thailand's 2006 decision to import generic versions of the antiretroviral medicine efavirenz from India under compulsory licence. This decision was met with hostility from the manufacturer, Merck, and the United States Government, which questioned the legality of the compulsory licence and pressed Thailand to rescind its decision. Thailand's subsequent decision to issue two further compulsory licences in 2007 for lopinavir/ritonavir and clopidogrel also resulted in retaliatory measures. In response, Abbott withdrew from the Thai market all medications awaiting registration and refused to register any new pharmaceutical products in the country, thereby denying patients access to the heat resistant form of lopinavir/ritonavir for which no generic equivalent existed,[i] although it later rescinded its decision. The European Trade Commissioner wrote to the Thai government criticizing its use of compulsory licences as "detrimental" to medical innovation, noting that such approaches could lead to Thailand's isolation from the global biotechnology investment community and urging negotiations with Sanofi-Aventis and other right holders.[ii] The United States Trade Representative elevated Thailand to its Priority Watch List in the Special 301 Report and withdrew duty-free access to the American market for three Thai products under the United States Generalized System of Preferences.[iii]

A letter from the Permanent Mission of Colombia to the United Nations, as well as letters from civil society groups addressed to the co-chairs of the High-Level Panel, brought to light developments in Colombia.[iv] In early 2016, the Ministry of Health of Columbia adopted resolution 2475, declaring that access to imantib, a medicine that appears on the WHO Essential Medicines List, was of "public interest" for the treatment of leukaemia.[v] The resolution was a pathway for the issuance of a compulsory licence. The letters chronicle attempts by various domestic and foreign parties to dissuade the Colombian government from issuing a compulsory licence as provided for by the TRIPS Agreement and the Doha Declaration.

[i] Wibulpolprasert, S., *et al.* (2011) Government use licenses in Thailand: The power of evidence, civil movement and political leadership. *Globalization and Health,* 7(32)).

[ii] A copy of the letter is available from: https://www.wcl.american.edu/pijip_static/documents/mandelson07102007.pdf [Accessed 9 September 2016].

[iii] Yamabhai, I., *et al.* (2011) Government use licences in Thailand: An assessment of the health and economic impacts. *Globalization and Health,* 7(28); ITPC (2015). The campaign for use of compulsory licensing in Thailand. *Make Medicines Affordable* [online]. Available from: http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/ [Accessed 28 June 2016].

[iv] The letters from the Permanent Mission of Colombia to the United Nations and civil society groups are available from:
http://www.mision-salud.org/2016/07/06/carta-abierta-al-panel-de-alto-nivel-sobre-acceso-a-medicamentos-de-las-naciones-unidas/ [Accessed 9 September 2016]
http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d2e998cd0f68c542159efc/1473440152256/Letter+from+Colombia.pdf [Accessed 9 September 2016]

[v] The resolution is available from: https://www.minsalud.gov.co/Normatividad_Nuevo/Resoluci%C3%B3n%202475%20de%202016.pdf

There are also instances where undue political and economic pressures have been used to dissuade governments from using the flexibilities that could protect public health.[121] Any form of undue pressure by governments designed to penalize other governments for exercising any of the powers they enjoy pursuant to the flexibilities available in the TRIPS Agreement violates the integrity and legitimacy of the system of legal rights and duties created by TRIPS, as confirmed by the Doha Declaration. Such actions undermine the efforts of governments to meet their human rights obligations as well as their inalienable duty to protect health. Should governments make full use of the flexibilities in the TRIPS Agreement, they can protect and advance public health objectives. WTO Members must help safeguard the legitimate rights of individual Members to adopt and implement flexibilities in the TRIPS Agreement as reaffirmed by the Doha Declaration.

The political pressure exerted on governments to limit the use of TRIPS flexibilities in some instances has been accompanied in recent years by a proliferation of initiatives aimed at intensifying intellectual property protection and enforcement measures. TRIPS-plus provisions in recent free trade agreements, such as the TPP, or in agreements concluded as a condition for acceding to the WTO, exacerbate these incoherencies by expanding intellectual property protection and enforcement and corporate prerogatives to unprecedented levels. The TPP, inter alia, grants exclusivity to test data, including new indications for existing medicines and biologics (medical products derived from living organisms). TRIPS-plus provisions generally extend the scope of what is patentable and also the duration of exclusivity protection. Dispute resolution under the TPP has turned what were previously civil infractions, such as trade secret theft, into criminal offenses.[122]

The duty borne by governments to protect the rights of their citizens by using TRIPS flexibilities extends to the conclusion of TRIPS-plus commitments. Agreeing to TRIPS-plus provisions in the hopes of gaining market access for agricultural or manufactured goods first requires empirical evidence of the consequences. Failure to conduct robust impact assessments before concluding such agreements is tantamount to a neglect of state duties to safeguard the right to health.

Box 8: Examples of TRIPS-plus provisions[123]

TRIPS-plus provision	**Examples of their use in trade agreements**	**Explanation**
Patents for new uses or methods of using a known product	US-Korea Free Trade Agreement (FTA) (Art. 18.8(1)); US-Australia FTA (Art. 17.9(1)); TPP (Art. 18.37(2)).	Governments must provide patent protection for new uses or methods of using known products.
Prohibition on pre-grant patent opposition	US-Singapore FTA (Art. 16.7(4)); US-Korea FTA (Art. 18.8.4).	Prohibition on challenges to the validity of a patent prior to issuance.
Test data exclusivity periods	WTO TRIPS Checklist for Russian Accession (WT/ACC/9, p. 13); US–Chile FTA (Art. 17(10)(1)); US-Morocco FTA (Art. 15(10)(1)); US–Bahrain FTA (Art. 14(9)(1)(a)); US–Singapore FTA (Art. 16(8)(1)); US-Australia FTA (Art. 17(10)(1)); TPP (Arts. 18.50 and 18.51).	Drug regulatory authorities cannot use or rely on clinical studies and data developed by the originator company to register the generic equivalent of a medicine for a given period of time following registration.

Patent term extensions for 'unreasonable' regulatory or marketing delays	Dominican Republic-Central America Free Trade Agreement (CAFTA-DR) (Arts. 15(9)(6) and 15(10)(2)); US-Bahrain FTA (Art. 14(8)(6)); US–Chile FTA (Arts. 17(9) and 17(10)(2)(a)); US–Singapore FTA (Arts. 16(7)(7) and 18(8)(4)(a)); US–Australia FTA (Arts. 17(9)(8) and 17(10)(4)); US–Morocco FTA (Arts. 15(9)(7) and 15(10)(3)); TPP (Arts. 18.46(3) and 18.48(2)).	Patent terms are extended in case of 'unreasonable' delay caused by drug regulatory authorities or patent offices in granting regulatory or marketing approval.
Patent linkage	Arts. 19(5)(3) of CAFTA-DR; 17(9)(4) of US–Chile FTA; 15(9)(6) of US–Morocco FTA; 16(7)(5) of US–Singapore FTA; 14(8)(5) of US–Bahrain FTA; Art. 18.53 of TPP.	Drug regulatory authorities cannot approve a generic version of a medicine that is under patent without the consent of the patent holder, thereby obliging public authorities to 'enforce' private intellectual property rights.
Limits on compulsory licensing grounds	US-Jordan FTA (Art. 4(20)); US-Singapore FTA (Art. 16(7)(6)); US-Australia FTA (Art. 17(9)(7)).	The use of compulsory licences is confined to specific circumstances, for example, remedying anti-competitive practices.
Limits on parallel imports	US-Morocco FTA (Art. 15(9)(4)); US-Australia FTA (Art. 17(9)(4)); US–Singapore FTA (Art. 16(7)(2)).	The importation of pharmaceutical products from other markets under the principle of international or regional exhaustion is restricted or entirely prohibited.
Enforcement of intellectual property rights	US-Singapore FTA (Art. 16.9); US-Vietnam FTA (Arts. 14-15); Japan-Indonesia FTA (Arts. 119, 121); Japan-Malaysia EPA (Art. 127); Japan-Thailand EPA (Art. 140); US-Vietnam FTA (Art. 14.1); US-Australia FTA (Art. 17.11(27)); US-Laos FTA (Art. 25); TPP (Art. 18.76).	Enhanced obligations regarding border measures, civil and administrative procedures, remedial provisions and the criminalization of certain violations beyond what is required by the TRIPS Agreement.

2.5 Intellectual property generated from publicly-funded research

Because the United States plays a central role in global innovation, its R&D and access policies influence other actors, including private and public sector donors and foundations, and impact on access to the fruits of technology worldwide. The National Institutes of Health (NIH) of the United States is by far the largest funder of health technology innovation, contributing over US$ 26 billion in 2013.[124] In 1980, the United States Congress enacted the Bayh-Dole Act, which, under the stated objective of promoting utilization of publically-supported inventions through institutional use of patents,[125] ushered in a new model of incentives for federally-funded academic R&D.

Bayh-Dole represented a significant departure from the status quo. Prior to 1980, the general practice at most academic research institutions was to share scientific findings through publication, and inventions arising from federal funding had to be assigned to the federal government, while very few were licensed out.[126] Now under Bayh-Dole, universities and public research institutions are allowed to patent the results of federally-funded research and to license private enterprises to develop them.[127] The United States Government retains a non-exclusive license to practice under the patent rights and the right, under specific circumstances, to license the invention to a third party, without the consent of the patent holder. Other governments have since passed laws modelled on Bayh-Dole.[128]

The Bayh-Dole Act has played a prominent role in the commercialization of biomedical technologies. Between 1980 and 2010, 154 FDA-approved medicines that were developed at United States research institutions were brought to market.[129] While Bayh-Dole has been credited with spurring economic development in the United States, royalty revenue—with important exceptions—is generally not that profitable for the patent holder. Universities, at times, pressure researchers to patent their work, seeing royalties as a potential revenue source, which in many cases isn't significant. For example, in 2006, United States universities, hospitals and research institutions derived US$ 1.85 billion from technology licensing compared to US$ 43.58 billion from federal, state and industry funders that same year. Technology licensing in that year accounted for less than 5% of total academic research dollars.[130]

Although intended to speed the transfer of scientific discovery from lab to marketplace for public benefit, critics contend that Bayh-Dole has had some unintended consequences, particularly when scientific research is constrained by the existence of a patent.[131] For example, indiscriminate patenting of research tools can potentially create unnecessary hurdles to accessing materials and technologies necessary for basic research.

Bayh-Dole allows recipients of federal support to negotiate flexible licensing terms and conditions, including through the use of voluntary licenses, or choosing to publish and to not seek patent protection, among others. But because many inventions licensed under Bayh-Dole are very early in the development stage, publicly-funded researchers often opt for exclusive licenses, hoping to recoup higher returns on their investment. However, without proper checks and balances in the license agreements, this exclusivity may inhibit access.[132]

Open models of innovation, which are generally patent free and often rely on quick, straightforward licensing, have been successful, particularly in the early phase of biomedical research. In this model, partners work collaboratively, driving new fields of science and expanding the knowledge base for all, thereby hastening progress towards the development of medical tools. Such partnerships can be between and among industry partners or as part of public-private partnerships. Collaborating on precompetitive activities, for example, can help solve thorny technical challenges, better understand the aetiology of disease, validate potential novel medicine targets or identify biomarkers to ascertain if a health technology is working. This open model is especially important to lower the hurdles of entry and accelerate the pace of development of health technologies, including those needed to combat emergent diseases.[133]

Health technologies developed with public funds at universities can be lifesaving for individuals and populations far removed from the academic institutions in which they were invented. In many instances, public funds are used to support clinical trials, comparative effectiveness trials or trials undertaken during global health emergencies. This public support is vital to tackling the health needs of populations and is strongly encouraged. However, concerns often arise that the public pays twice: first through taxpayer support for research and then when purchasing the resulting health technologies at escalating prices.[134]

For the public to reap the full benefit of the public investment in research, public funding agencies must ensure that, when feasible, data, results and knowledge generated from such public investment be made broadly available. Such availability might be achieved, for example, through strong, enforceable policies on data sharing and data access that are a condition of grant awards, by creating data repositories and by establishing normative data standards that can be adopted and used by the biomedical community. In all cases, public funding agencies should strongly encourage patenting and licensing practices that benefit public health, including the use of non-exclusive licences, donation of intellectual property rights, participation in public sector patent pools and other mechanisms that can maximize innovation while promoting access.

In the context of licensees with implications for resource-limited settings, public health-sensitive provisions for the management of intellectual property deriving from publicly-funded research (sometimes referred to as global access licensing provisions) can be pursued. Over the past two decades, some universities and public funding institutions have begun to explore and put such provisions and frameworks into place.[135] These provisions seek to promote technology transfer and access by requiring differentiated licensing terms and conditions according to a number of factors such as geography, income, manufacturing and distribution costs, among others.

2.6 Recommendations

2.6.1. TRIPS flexibilities and TRIPS-plus provisions

World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies. More specifically:

(a) WTO Members must make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred.

  (i) The United Nations Conference on Trade and Development (UNCTAD), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) should cooperate with one another and with other relevant bodies with the requisite expertise to support governments to apply public health-sensitive patentability criteria.

  (ii) These multilateral organizations should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

(b) Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.

(c) WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

(d) Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities. Instances of undue political and commercial pressure should be formally reported to the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.

(e) Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they must undertake public health impact assessments. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.

2.6.2 Publicly-funded research

(a) Public funders of research must require that knowledge generated from such research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research.

(b) Universities and research institutions that receive public funding must prioritize public health objectives over financial returns in their patenting and licensing practices. Such practices may include publication, non-exclusive licensing, donations of intellectual property and participation in public sector patent pools, among others. Sufficient incentives must be in place in these practices to make it attractive for developers to underwrite the cost of bringing a product to market at affordable prices that ensure broad availability.

(c) Universities and research institutions that receive public funding should adopt policies and approaches that catalyse innovation and create flexible models of collaboration that advance biomedical research and generate knowledge for the benefit of the public.

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3. NEW INCENTIVES FOR RESEARCH AND DEVELOPMENT OF HEALTH TECHNOLOGIES

Market-driven R&D has been credited by some for producing a number of important health technologies that have improved health outcomes significantly throughout the world. But serious gaps, both in innovation and access, persist. Under the prevailing model, the biomedical industry, with the help of well-established intellectual property protection mechanisms, test data exclusivity and significant public funding of research, invests in R&D, obtains marketing approval and pays for related expenses by charging prices that allow them to recover these substantial costs and generate a profit. Shareholders who invest in biomedical companies do so with the expectation of generating a return on investment.

While this system has resulted in innovative products coming to the market, it also has created important tensions because of high prices, and fuelled policy incoherencies through the application of exclusivity-driven business models. Because this system is predicated on the ability to generate profit, governments and the biomedical industry have often failed to deliver new health technologies for diseases that do not, and cannot, promise high returns—those that mostly afflict the poor regardless of where they may live.[136]

Antimicrobial resistance is a global public health threat, whose impact and proportions have the potential to kill millions of people. Yet, AMR represents a fundamental commercial dilemma for private sector companies: developing new antibiotics is often an expensive, long-term proposition. The resulting medicines, to retain their power and effectiveness, must be used judiciously and for a limited time, which limits the market potential and curtails profits. The private, public and non-profit sectors all concur that the market will not solve this problem and that special interventions to address this situation need to be enacted.[137]

In contrast, R&D funding for rare diseases, once largely forgotten because of the low returns on investment that results from the small number of people afflicted, is increasing. This is due to several factors: advances in technology, particularly for genetically-linked diseases, and strong pressure and funding from patient advocacy groups. This is accompanied by the realization by private sector companies of the significant profit potential that rare disease treatments can have, particularly in wealthier countries.[138]

Various efforts are being undertaken by governments, international organizations, the private sector, philanthropic organizations and civil society to promote R&D for unmet health needs. However, the absence of a robust priority-setting mechanism for health R&D has exacerbated policy incoherencies. Naturally, public funders of health R&D are established under national laws and are accountable to national governments. Therefore, they are not held accountable by the international community for failing to prioritize global health needs.[139]

3.1 Delinking the costs of research and development from the end product

There are numerous mechanisms and tools now in use that provide new incentives for health technology innovation.[140] Some of these have been around for many years and are discussed, for instance, in the 2006 report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health.[141] What many have in common is that they incorporate aspects of delinkage. These mechanisms fall into several categories, which often intersect, including the following:

- **Push** mechanisms are upfront grants and in-kind contributions that get a project off the ground and into the market by mitigating the prohibitive costs of R&D or its most expensive parts, such as Phase III clinical trials.
- **Pull** mechanisms promise financial rewards after an objective or milestone has been reached. Rewards may include incentives, such as tax breaks, prizes or so-called advance market commitments, by which procurers commit to buy a certain amount of medicines or vaccines from a producer.[142]
- **Pooling** aggregates funding, data and intellectual property or related proprietary information to facilitate sharing of data and expertise for production of the final products.
- **Open collaborative research** platforms, like the Open Source Drug Discovery consortium, enable researchers from various disciplines and countries to work together to solve complex challenges encountered during upstream research.
- **Public-private partnerships and product development partnerships**, which may be funded by some of the delinkage mechanisms described above, synergize both the resources and strengths of the private and public sectors.[143] By eliminating or significantly limiting exclusivities, PDPs can make their products widely available as global public goods.

Philanthropies and governments generally provide around 90% of PDP funding.[144] Prominent global health and development organizations, together with industry partners, adopted the London Declaration on Neglected Tropical Diseases in 2012, with the aim of expanding R&D partnerships and monitoring progress towards NTD eradication by 2020.[145] In 2014, most global funding of R&D for neglected disease research went directly to researchers (72%) with around 22% (or US$ 526 million) going to PDPs.[146] The two largest philanthropic investors—the Bill and Melinda Gates Foundation and the Wellcome Trust—together contributed US$ 660 million on R&D in NTDs in 2014.[147] A number of other funds have been established in recent years to support R&D for health technologies to address neglected areas,[148] and these commitments are helping revitalize health technology innovation in these areas.

In January 2016, representatives of the pharmaceutical, biotechnology and diagnostics industries adopted a Declaration on Combating Antimicrobial Resistance. The declaration, adopted by almost 100 companies and 11 industry associations as of the end of June 2016, commits signatories to increasing investment in R&D by extending collaborative initiatives between industry, academia and public bodies to increase and improve research into new antibiotics, diagnostics, vaccines and other alternative treatments.[149] As important as these efforts may be, the fact remains that the production of health technologies for many diseases is far from sufficient and current efforts do not offer enough long-term, sustainable solutions.[150]

WHO has taken leadership with its Global Action Plan on Antimicrobial Resistance (GAP-AMR), which combines new medicine discovery, development and stewardship.[151] The WHO Global Antibiotic Research and Development Partnership (GARD)—formed with the Drugs for Neglected Diseases initiative (DNDi) and engaging industry, PDPs, academia, civil society and national health authorities from countries of all income levels—is a promising initiative to develop new antibiotics which are suitable for resource-limited settings.[152] Political commitment is important to ensure that this nascent partnership is adequately resourced. The European Union's Innovative Medicines Initiative is working on economic stimulants for antibiotics R&D.[153]

These efforts are characterized by an understanding that global challenges, such as AMR, require multifaceted approaches and multilateral planning and coordination.[154] For this, the three mechanisms that can be used to implement delinkage as outlined by the WHO Global Strategy and Plan of Action (2008) are: priority setting, financing and coordination.[155]

In spite of encouraging signs, many are pessimistic that this miscellany of new approaches will never be equal to the needs left unfulfiled by the market model. Consensus and demand are growing for a coordinated global R&D agenda, buttressed by solid financial commitments from governments. Significant work has been done toward this goal, as set forth in the WHO Global Strategy and Plan of Action and the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). While the CEWG work plan continues to be discussed at consecutive World Health Assemblies, progress is slow given the immediacy of the challenge.[156]

3.2 Priority setting and coordination

The 2030 Agenda stresses the need for "quality, accessible, timely and reliable disaggregated data" to measure progress, inform decision-making and ensure that no one is left behind.[157] There is wide agreement on the importance of comprehensive and accurate models and "metrics for evaluating performance, setting targets, guiding the distribution of scarce health resources and advancing access to affordable medicines."[158] Toward this end, the WHO Global Observatory on Health Research and Development, still in pilot stage, aims to provide a centralized and comprehensive source of data from diverse sources on what health R&D is being conducted globally, where it is being conducted, by whom and how. One of the Observatory's goals is to identify R&D gaps and opportunities and define priorities for new R&D investments.[159]

An example of such priority setting is the WHO R&D Blueprint, an initiative of preparedness and response to emerging pathogens that could cause severe outbreaks but for which there are no medical countermeasures.[160] However, the Blueprint has only been used once—during the 2014-2015 Ebola outbreak, after which the United Nations Secretary-General established a High-Level Panel on Global Response to Health Crises. The robustness and replicability of the WHO R&D Blueprint has yet to be assessed.

Among its findings, that High-Level Panel noted that the "high risk of major health crises is widely underestimated, and that the world's preparedness and capacity to respond is woefully insufficient." [161] R&D on emerging infectious diseases can be considered critical to the welfare of nations as well as for cross-border security that it should be considered a part of national security budgets.[162] Analysis of the temporal pattern of emerging infectious disease (EID) events over the last six decades predicts the emergence of five new EIDs each year if no mitigation policies are adopted now.[163]

But how will all of this be paid for? Recent EID events offer a stark reminder of the need for delinkage. Prior to 2014, Ebola outbreaks were primarily confined to remote regions of West Africa, where the majority of residents live on less than a dollar a day.[164] Prior to 2015, Zika was an obscure virus that received little attention from the global community.[165] No one expected either virus to leave its endemic borders or spread so rapidly. Consequently, no vaccines were developed. Promising Ebola therapies languished in preclinical R&D for over ten years without funding.[166] Rapid point-of-care diagnostics could have protected health workers in the 2014-2015 Ebola outbreak, eased overburdened treatment centres and reduced patient loss to follow-up.[167] Instead, a reported 11,310 of the 28,652 people infected died.[168]

3.3 Financing

Ideas for collaborative health-related R&D and alternative patent and licensing structures and financing mechanisms abound, but stakeholders are now calling for action. "An absolutely necessary condition for implementing [delinked R&D] approaches will be a sustainable source of funding," the CEWG noted in its 2012 report.[169] Where will the financing to turn ideas into action come from? Greater public financial commitments—and accountability for those commitments—are necessary.[170] At present, the major share of global biomedical R&D is concentrated in the United States, European countries and Japan.

While the major share of health technology R&D financing is borne by the private sector, untapped opportunities for increasing private sector funding still exist. The final report of the United Kingdom Government-convened 'Review on Antimicrobial Resistance' contains a proposal calling on governments to consider a small levy on the pharmaceutical sector. This proposal merits careful consideration by governments as one way to increase funding for market entry rewards for new antibiotics.[171] Initiatives by governments, the private sector and non-government actors to incentivize upstream research should also be carefully considered.

A much greater funding responsibility, however, must be shouldered by governments, as they bear responsibility to their citizens to progressively realize the highest attainable standard of health. The report of the Review on AMR, for example, calls for a Global Innovation Fund of up to US$ 2 billion over five years to incentivize the development of new antibiotics and other unmet health needs.[172] Other initiatives awaiting funding by governments include a proposal for a Health Product R&D Fund discussed in a recent report of the Special Programme for Research and Training in Tropical Diseases (TDR)[173] and the so-called "demonstration projects" approved by the World Health Assembly to demonstrate effectiveness of new, innovative and sustainable financing and coordination approaches to address identified R&D gaps.[174]

Four years ago, the CEWG recommended that the United Nations set targets, based on Gross Domestic Product, for government funding of health-related R&D. This would involve both national spending and commit wealthier countries to help poorer ones. The CEWG proposed a binding R&D treaty or convention to hold governments to those commitments. While that proposal has increasingly gathered support, negotiations at WHO are proceeding slowly.[175]

Considering the limits to financing public health R&D through domestic taxation, private philanthropy and official development assistance, innovative sources of financing, such as taxes on global transactions, have the potential to overcome this constraint. Progress has been made in recent years, for instance, through the leadership of the Leading Group.[176] As affirmed in the Addis Ababa Action Agenda on Financing for Development, more countries should join in the effort to develop and implement new and innovative sources of financing public R&D.[177] All these, as well as new opportunities and, if necessary, alternative forums should be explored.

To resolve incoherence between market exclusivity-driven approaches and policies that steer investment and attention to where they are most needed, some current initiatives should be scaled up and other new ones created. The obligation of governments to uphold the right to health is not conditional on the availability of effective R&D mechanisms. Governments must therefore lead the private sector, civil society and other stakeholders in building coordinated public health R&D systems and financing them equitably, accountably and sustainably.

Box 9: The case of antimicrobial resistance

AMR is one of the most crucial health problems facing the world today. New models of R&D are under consideration and delinkage may provide the most useful path forward to address AMR. A successful strategy requires as a minimum global coordination and prioritization, sustainable and predictable funding for R&D from basic research through set stages of clinical development, collaboration between and among government, academia and the private sector, management of intellectual property, regulatory convergence, manufacturing capacity, implementation of surveillance and preservation mechanisms and education.

The High-Level Panel recognizes the trailblazing work of recent reviews, commissions and the unprecedented high-level meeting at the United Nations on AMR. The High-Level Panel also recognizes that it is imperative to sustain and enhance this momentum and recommends the establishment of an independent international committee responsible for assessing, coordinating and mapping R&D developments in this field. This international committee should also be charged with assisting in resource mobilization and ensuring the efficient allocation and use of funds so that antimicrobial medicines and point-of-care diagnostics will be available and accessible to those most in need.

Such an international committee should be charged by the United Nations to provide policy, regulatory and institutional direction on the issue of AMR, working in partnership with WHO and the various public and private sector initiatives directed at addressing the urgent need for the development of new tools. The High-Level Panel emphasizes that market-based models of innovation for AMR are unsustainable. Funding for R&D to address AMR and related challenges must be operationalized through delinkage models. Indeed, the challenge of AMR represents an important and incontestable context in which the viability of delinkage innovation models can be fully explored.

3.4 Recommendations

(a) It is imperative that governments increase their current levels of investment in health technology innovation to address unmet needs.

(b) Stakeholders, including governments, the biomedical industry, institutional funders of healthcare and civil society, should test and implement new and additional models for financing and rewarding public health research and development (R&D), such as the transaction taxes and other innovative financing mechanisms.

(c) Building on current discussions at the WHO, the United Nations Secretary-General should initiate a process for governments to negotiate global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all. Such a Convention should focus on public health needs, including but not limited to, innovation for neglected tropical diseases and antimicrobial resistance and must complement existing mechanisms.

(d) As a preparatory step, governments should form a Working Group to begin negotiating a Code of Principles for Biomedical R&D. The Principles would apply to public R&D funds and should also be adopted by private and philanthropic funders, product development partnerships, universities, the biomedical industry and other stakeholders. Governments should report annually on their progress in negotiating and implementing a Code of Principles as a preparatory step to negotiating the Convention in the United Nations General Assembly.

4. GOVERNANCE, ACCOUNTABILITY AND TRANSPARENCY

Good governance,[178] accountability, stakeholder participation and transparency are decisive enablers and part and parcel of the 2030 Agenda.[179] The rules governing human rights, trade and public health exist in separate but overlapping spheres; their implementation rests at different levels. An important factor behind the incoherence between trade, intellectual property laws, human rights and public health lies in the different accountability mechanisms and uneven levels of transparency.

Human rights place a legal obligation on governments to progressively realize the right to health. Yet, in the context of health technologies, trade and investment agreements regularly contain TRIPS-plus provisions that increase levels of intellectual property protection and enforcement that impede the ability of governments to use laws and policies promoting their human rights obligations to the fullest extent possible. Trade and intellectual property-related accountability mechanisms are typically regulated by the WTO Dispute Settlement Understanding and the relevant dispute settlement provisions within a free trade agreement or related treaty. On the other hand, existing human rights accountability mechanisms are characterized by varying degrees of precision, legal weight and enforceability.[180]

Transparency is a core component of good governance. Civil society and patient groups rely on transparency of information to hold government authorities, private sector companies and international organizations accountable. Transparency can ensure fairness during negotiations that take place between biomedical companies and procurement organizations. The work of regulatory authorities in enhancing both innovation and access could be significantly aided if accurate information on the costs of R&D, production and distribution of health technologies were available. Most regulatory authorities already mandate the disclosure of information on quality, safety and efficacy of health technologies and some encourage information sharing on investments made in the R&D of health technologies. However, this information can be difficult to disaggregate.

Another area heavily affected by the lack of transparency and stakeholder participation is the negotiation and setting of trade rules. Human rights treaties, United Nations General Assembly and Security Council resolutions, various public health and human development commitments, like the SDGs, are debated, negotiated and committed to publicly. While the principles of the WTO require that negotiations should be transparent,[181] in practice and in other forums, trade and investment agreements are often negotiated in secrecy. The lack of transparency in trade negotiations typically limits the ability of civil society, patient groups, labour unions, consumer associations, health professionals and even parliamentarians to assess the human rights and public health impacts and to hold governments accountable. Any robust and effective accountability framework for improving innovation and access to health technologies requires coherence and coordination across sectors and multiple layers of oversight, including in the political, administrative, legal and social realms. The framework must be grounded in human rights and all stakeholders—especially patient representatives, civil society and parliamentarians—must be enabled, supported and legally protected to effectively participate at every stage.

4.1 Governance and accountability

Multilateral organizations, governments, the private sector and civil society all have a critical role to play in governance and accountability for innovation and access to health technologies, including with regard to increasing transparency.

4.1.1 International and multilateral organizations and governance and accountability

Policy incoherencies among human rights, trade and public health are echoed in the United Nations and in the related organizations that support Member States to address these issues.[182] Many international organizations and United Nations entities that work on issues of health technology innovation and access operate under differing governance structures with different mandates that makes collaboration and coherence challenging.[183] The activities undertaken by these organizations and the policy advice they provide to governments and other stakeholders in accordance with their mandates can often amplify the incoherencies between human rights, trade rules and public health objectives.[184]

WHO, WIPO and WTO have strengthened their collaboration on health technology innovation and access in recent years, but do not necessarily take into account or align with the work of the Office of the United Nations High Commission for Human Rights (OHCHR), the United Nations Industrial Development Organization (UNIDO) the Joint United Nations Programme on HIV/AIDS (UNAIDS) or UNDP. Mechanisms such as interagency working groups can help to improve coordination between the different agencies and ensure greater coherence in the advice and support to governments and other stakeholders. Precedents exist for improving collaboration and coordination through interagency entities such as the United Nations Development Group, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the recently established United Nations Interagency Task Force on the Prevention and Control of Noncommunicable Diseases.[185]

The 2030 Agenda calls for "robust, voluntary, effective, participatory, transparent and integrated" mechanisms of "follow-up and review" of Member State progress toward the SDGs.[186] This requires that reporting mechanisms be put in place by governments to monitor progress and identify gaps in meeting requirements.

The Millennium Development Goals (MDG) Gap Task Force was established by the Secretary-General of the United Nations in 2007 to improve monitoring of the global commitments contained in MDG 8: 'Develop a Global Partnership for Development.'[187] One of the five core elements on which the taskforce systematically reported was health technology innovation and access. However, the incoherencies between human rights, trade rules and public health were not addressed in the reports. The impact of the taskforce reports in influencing health technology innovation and access initiatives is unknown, largely because there were no accountability mechanisms attached to its reporting. In 2010, when progress was lagging on the health of women and children, the Secretary-General of the United Nations created a Commission on Information and Accountability for Women's and Children's Health to make recommendations on advancing progress. In turn, the Commission set up an Independent Expert Review Group to monitor and report on the degree to which states and non-state actors were implementing those recommendations.[188] The models could also be used for improving accountability for health technology innovation and access, including to follow up on this High-Level Panel's recommendations.

4.1.2 National governance, accountability and civil society

The effective drafting and implementation of national legislation to incentivize health technology innovation and the negotiation of trade agreements requires the participation of multiple government departments and ministries, whose mandates overlap and intersect. The most obvious of these are trade, commerce and industry, economic development, science and technology, health, justice, foreign affairs, finance and national planning. Countries ranging from Lesotho to Switzerland have improved domestic policy coherence by bringing representatives of several ministries together under an authoritative head in working groups on health technology innovation and access.[189] In most countries, however, these groups do not exist. Where they do, their functioning is usually ad hoc and beset by the asymmetries of influence that exist across most governments.[190]

An important tool to promote government accountability is independent 'shadow reporting' to United Nations bodies, which can help to highlight unaddressed issues, misinformation and/or problematic conduct.[191] But many of the stakeholders, such as civil society and patient groups who produce shadow reports, operate in an environment of dwindling financial resources, suppression of civil society activity and declining access to platforms where human rights, trade and public health rules are negotiated and monitored. They need adequate resources and space for shadow reports as well as to advocate for improving innovation and access to health technologies.[192]

Human rights and public health impact assessments are another important modality for holding governments accountable for their actions in negotiating and concluding trade agreements that may adversely impact the right to health. The fundamentals of human rights impact assessments are outlined in the United Nations Guiding Principles on Business and Human Rights, proposed by John Ruggie, the United Nations Special Representative for Business and Human Rights, and endorsed by the United Nations Human Rights Council in 2011.[193] Known as the 'Ruggie Principles,' these are guidelines for states and companies to prevent, address and remedy human rights abuses committed in business operations. Calls for human rights impact assessments of health technology innovation and access are gaining ground with experts in human rights, health and development.[194] The Ruggie Principles distinguish between a private business's responsibilities and a state's binding obligations and establish a hierarchy of three core principles: 1) the state duty to protect against human rights abuses by third parties, including businesses; 2) the corporate responsibility to respect human rights; and 3) the need for more effective access to remedies for failure to abide by these responsibilities.[195] In other words, governments are ultimately responsible for safeguarding human rights. Concomitantly, governments must apply "appropriate and effective remedies when [those laws are] breached." [196] Other UN and multilateral organizations and bodies have issued guidelines and clarifications on the obligations of businesses.[197] But those remedies largely remain to be enacted and enforced.

In June 2016, the CESCR released some important observations on the conduct of state parties when concluding trade agreements. The Committee urged state parties to the ICESCR to undertake consultations with relevant stakeholders, including engaging affected communities in the development stages of negotiation and ratification of trade agreements, based on an assessment of expected impacts, and to ensure that an impact assessment is systematically conducted during implementation to adapt, if necessary, the content of the commitments.[198] This important development signals a growing sense of government accountability to ensure that the consequences of trade-related commitments entered into are carefully considered and involve participation of key stakeholders, including civil society.

4.1.3 Corporate governance and accountability

Various voluntary and market-based mechanisms are set up to encourage greater accountability among corporations for innovation and access to health technologies, including greater public scrutiny. However, with monitoring and ranking mechanisms, such as the Access to Medicines Index, it is difficult to assess the effect of the rankings on company policies and practices.[199]

The Ruggie Principles call on companies to conduct "due diligence" to "identify, prevent, mitigate and account for how they address their adverse human rights impacts," redress their failures and publicize their remedial actions.[200] Some pharmaceutical companies do this and report on it as part of their annual reporting process.[201] The United Nations Global Compact on corporate social responsibility, currently signed by more than 8,902 companies in over 166 countries, encourages transparency through annual Communication on Progress reports on sustainability.[202] Voluntary corporate social responsibility, while laudable, is limited by the fact that any action taken by companies is exactly that—voluntary in nature.

4.2 Transparency

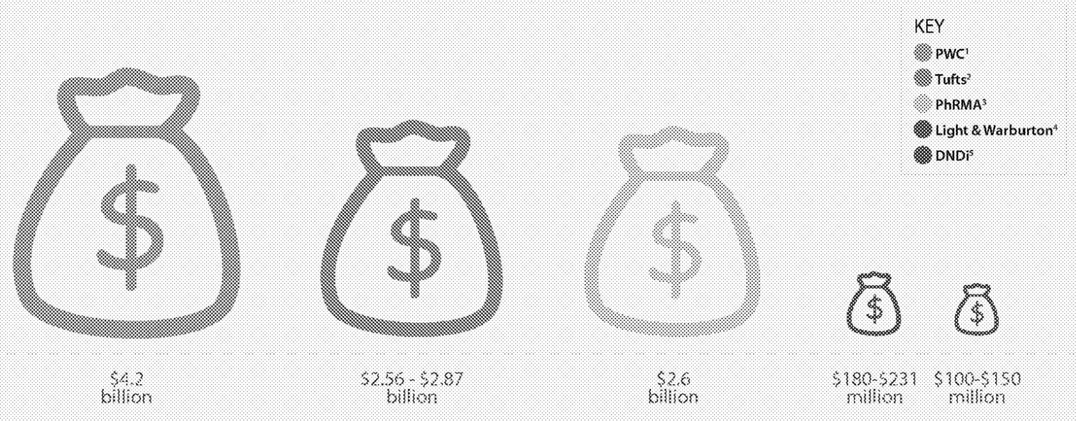
4.2.1 R&D costs and pricing of health technologies

To realize a fair public return for public investment, government actors and public funders should require clear information on what it costs to innovate and bring a particular health technology to market. Although publicly-traded companies are legally required to disclose a range of financial information in their annual report, privately held ones are not, and even when disclosed, the data can be incomplete and difficult to parse and may not be sufficiently disaggregated, for example between R&D costs and marketing costs. For instance, R&D costs are not broken down by product, nor are precise sources of income listed in many cases, so a research grant from a government agency may not appear in a grantee's books depending on accounting practices and the levels of funding involved.[203] Ultimately, cost estimates vary widely depending on the source.

For instance, a 2016 study conducted by the industry-funded Tufts Centre for the Study of Drug Development pegged the average total cost of bringing a new medicine to market at US$ 2.56 billion to US$ 2.87 billion.[204] Although often cited, this is a deeply contested figure.[205] In comparison, the non-profit DNDi analyzed its own R&D costs and found that it spent US$ 39 million to US$ 52 million developing a new chemical entity. Adjusting for the risk of failure, as originator companies usually do, the number from DNDi rose to US$ 130 million to US$ 195 million.[206] Of course, this cannot be taken as a direct comparison, given the significant disparities in R&D costs depending on the health technologies in question and the costs of operation. However, it does provide a window into the very large disparities that exist in R&D cost estimates. Marketing cost estimates show similar disparities. Industry authorities generally claim more is spent on R&D than on marketing, but an analysis by Canadian academics concluded the opposite.[207] More complete disclosure is needed to create reliable data on costs of health technology research, development and marketing. At present, this important information is scattered over numerous conflicting sources and much is missing.

Some public databases of medicine, vaccine, diagnostic and medical device prices exist. The WHO Global Price Reporting Mechanism (GPRM), for instance, records international transactions (volumes, prices, terms and other information) of HIV, tuberculosis and malaria medicines and diagnostics purchased by national programmes in low- and middle-income countries, as do other international organizations and governments.[208] The Vaccine Product, Price and Procurement web platform (V3P), another WHO initiative, provides information on vaccine product, price and procurement data.[209] Non-governmental organizations, such as Médecins Sans Frontières and Health Action International, have kept databases and produced publications to track the prices of key health technologies.[210] These mechanisms have strengths, but also limitations—such as the surveying of only some countries and some diseases. Furthermore, many complexities get in the way of confirming prices. Discounts, mark-ups, taxes and regional differences mean that prices vary within countries and final prices may not match list and factory prices.[211] Even in relatively transparent systems, published lists do not

R&D costs – a wide range of estimates



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always disclose pricing arrangements between suppliers and public procurers.[212] Timely, comprehensive and user-friendly databases on costs and prices are needed.

4.2.2 Clinical trials

Healthcare providers need complete, up-to-date clinical trial data to give patients the safest, best treatments. A 2013 United Kingdom parliamentary committee pointed out the serious problem of lack of information sharing from clinical trials: "Important information about clinical trials is routinely and legally withheld from doctors and researchers by manufacturers. This longstanding regulatory and cultural failure impacts on all of medicine and undermines the ability of clinicians, researchers and patients to make informed decisions about which treatment is best."[213]

Clinical trials are required by regulatory authorities before approval is given to manufacturers to enter the market and are meant to assure the safety and efficacy of health-related products. Clinical trials are also the biggest R&D expense.[214] Increased transparency of clinical trial information is an important contributor to improved public health outcomes. Secondary and meta-analyses may change clinical practices and reveal that interventions are ineffective or unsafe, as happened in the case of selective serotonin reuptake inhibitors antidepressants.[215] When baseline data is published on trial subjects' ages, gender and health conditions (while protecting patient confidentiality) doctors and health authorities can gauge the merits of a treatment for people with similar characteristics.

Clinical trial sponsors and scientists are guided by a patchwork of national laws and non-binding professional ethical standards for research involving human subjects.[216] But trials are not only conducted in the country where the product is discovered or developed and the health technologies are used around the world. A lack of coordination between national drug regulatory authorities can also delay registration of new heath technologies. Government regulators do not always enforce their own rules stringently.[217]

Transparency of clinical trials is not always a given. The initiators of trials commonly require non-disclosure agreements, in which the institutions that conduct the trials consent to keep the protocols, patient data and research results secret.[218] Some conductors of clinical trials have introduced bias into study designs and suppressed negative results,[219] although this does not appear to be common practice. To address the need for global transparency, several years ago WHO established the International Clinical Trials Registry Platform (ICTRP) that can serve as a single database where voluntarily-provided trial data can be made available. However, the ICTRP does not yet include any trial results, although work is underway to do so.[220] In 2014, the European Medicines Agency adopted a new policy to make clinical studies available.[221]

4.2.3 Patent information

Transparent patent information can be an important a determinant of health outcomes. When the status and details of intellectual property protections are easily accessible, competitors can confidently release cheaper health technologies similar to out-of-patent products.[222] Also, governments, generic companies, researchers and civil society can more easily review and oppose questionable patent applications and grants and monitor whether officials are applying patentability criteria as required by national laws.

Currently, patent information is often confusing, incomplete and fragmented. A single product may be protected by hundreds of patents[223] and compounds may appear under a brand name or an international non-proprietary name (INN). Patents pile up over time, with no indication as to which ones the holder plans to enforce[224] and extend. These factors, as well as excessive patenting, can impede scientific progress and legitimate competition.[225]

Multilateral organizations, such as WHO, WIPO and WTO, provide support to countries and procurement agents to navigate the mazes of patent information needed to make procurement decisions.[226] A number of countries and organizations publish patent databases and conduct surveys and analysis (referred to as "patent landscapes") covering certain fields of health technologies and groups of essential medicines, such as ARVs.[227] These efforts begin the process of creating a comprehensive source of global patent information—but like the data itself, they are still incomplete and scattered.

4.3 Recommendations

4.3.1 Governments

(a) Governments must review the situation of access to health technologies in their countries in light of human rights principles and States' obligations to fulfil them, with assistance from the Office of the United Nations High Commissioner for Human Rights (OHCHR) and other relevant United Nations entities. The results of these assessments should be made publicly available. Civil society should be financially supported to submit their own shadow reports on innovation and access to health technologies. Such national reviews should be repeated at regular intervals.

(b) Governments should strengthen national level policy and institutional coherence between trade and intellectual property, the right to health and public health objectives by establishing national inter-ministerial bodies to coordinate laws, policies and practices that may impact on health technology innovation and access. Appropriate member/s of the national executive who can manage competing priorities, mandates and interests should convene such bodies. The deliberations and decisions of such groups should operate with a maximum of transparency. Civil society should be financially supported to participate and submit their shadow reports on innovation and access to health technologies.

4.3.2 Multilateral organizations

(a) The United Nations Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access. Challenges and progress on innovation and access to health technologies under the ambit of the 2030 Agenda, as well as progress made in implementing the recommendations of this High-Level Panel, should be monitored by this body. Membership should comprise of representatives from United Nations and multilateral organizations, civil society, governments, academia and the private sector.

(b) The United Nations Secretary-General should establish an inter-agency taskforce on health technology innovation and access. This taskforce, operating for the duration of the SDGs, should work toward increasing coherence among United Nations entities and relevant multilateral organizations like the WTO. The taskforce, also charged with overseeing the implementation of the High-Level Panel's recommendations, should be coordinated by the United Nations Development Group and report annually to the United Nations Secretary-General on progress made in enhancing United Nations system-wide coherence.

(c) The United Nations General Assembly should convene a Special Session no later than 2018 on health technology innovation and access to agree on strategies and an accountability framework that will accelerate efforts towards promoting innovation and ensuring access as set out in the 2030 Agenda. Civil society should be financially supported to participate and submit their reports on innovation and access to health technologies at this Special Session.

4.3.3 Private sector companies_

(a) Biomedical private sector companies involved in health technology innovation and access should report, as part of their annual reporting cycle, on actions they have taken that promote access to health technologies.

(b) Private sector companies should implement the following:

(i) a publicly available policy on their contribution to improving access to health technologies setting out general and specific objectives, timeframes, reporting procedures and lines of accountability; and

(ii) a governance system that includes direct board-level responsibility and accountability on improving access to health technologies.

4.3.4 R&D, production, pricing and distribution of health technologies

(a) Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to:

(i) The costs of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and

(ii) Any public funding received in the development of the health technology, including tax credits, subsidies and grants.

(b) Building on the Global Price Reporting Mechanism (GPRM), V3P and others, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.

4.3.5 Clinical trials

(a) Governments should require that the unidentified data on all completed and discontinued clinical trials be made publicly available in an easily searchable public register established and operated by existing mechanisms such as the WHO Clinical Trials Registry Platform, clinicaltrials.gov or in peer reviewed publications, regardless of whether their results are positive, negative, neutral or inconclusive.

(b) To facilitate open collaboration, reconstruction and reinvestigation of failures, governments should require that study designs and protocols, data sets, test results and anonymity-protected patient data be available to the public in a timely and accessible fashion. Those undertaking clinical trials must not prevent researchers from publishing their findings.

4.3.6 Patent information

(a) Governments should establish and maintain publicly accessible databases with patent information status and data on medicines and vaccines. This information should be periodically updated and consolidated by WIPO in collaboration with stakeholders to develop an international, easily searchable database which should include:

- standard international common names for biological products;
- international non-proprietary names for products, either as known at the time of application or after the granting of a patent; and
- dates of grant and expiry.

END NOTES

[1] SDG Targets: SDG target 3.8 *"Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all"*; Target 3b, *"Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all."* (United Nations General Assembly (2015) Transforming our world: The 2030 Agenda for Sustainable Development, A/70/L.1. Available from: https://sustainabledevelopment.un.org/post2015/transformingourworld [Accessed 27 June 2016].

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[67] Bouchard, R., *et al*. (2010) Empirical analysis of drug approval-drug patenting linkage for high value pharmaceuticals. *Northwestern Journal of Technology and Intellectual Property,* 8(2), pp. 174-227.

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[70] Under NAFTA provisions, for example, the United States biomedical company, Eli Lilly, is suing the government of Canada for US$ 500 million over invalidation of two of the innovator company's patents. *Eli Lilly and Company v The Government of Canada*, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (Nov. 7, 2012). Available from: http://italaw.com/sites/default/files/case-documents/italaw1172.pdf [Accessed 3 June 2016]. More at: http://www.italaw.com/cases/1625 [Accessed 3 June 2016]. For further discussion of the impact of "foreign investor privileges" on TRIPS-plus standards of intellectual property protection, see Baker, B. and Geddes, K. (2015) Corporate power unbound: Investor-state arbitration of IP monopolies on medicines—Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement. *Journal of Intellectual Property Law*, 23(1), Art. 2.

[71] Musungu, S., Villanueva, S. and Blasetti, R. (2004) Utilizing TRIPS flexibilities for public health protection through south-south regional frameworks. *South Centre* [online]. Available from: http://apps.who.int/medicinedocs/pdf/s4968e/s4968e.pdf [Accessed 23 June 2016].

[72] Contribution (100) from Safiatou Simpore Diaz, YOLSE, March 2016. Available from: https://highlevelpaneldevelopment.squarespace.com/inbox/2016/3/4/safiatou-simpore-diaz-english-translation [Accessed 23 June 2016].

[73] For a full discussion see Elliot, R. (2016) International legal norms: The right to health and the justifiable rights of inventors, Background paper prepared with the High-Level Panel Secretariat at UNDP in collaboration with UNAIDS. *UNDP*

[online]. Available from: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56da14af4d088e1b940103a4/1457132721678/DRAFT+Background+Paper+B.pdf [Accessed 7 June 2016].

[74] For example, when Thailand issued a compulsory licence on the antiretroviral medication *lopinavir/ritonavir* in 2007, the patent-holder withdrew all of its pending registration applications and announced it would not launch any new medicines in that country, thereby denying access to the heat-resistant form of lopinavir/ritonavir for which no generic equivalent existed. See: Wibulpolprasert, S., *et al.* (2011) Government use licences in Thailand: The power of evidence, civil movement and political leadership. *Globalization and Health,* 7(32); Yamabhai, I., *et al.* (2011) Government use licences in Thailand: An assessment of the health and economic impacts. *Globalization and Health,* 7(28); ITPC (2015) The campaign for use of compulsory licensing in Thailand. *Make Medicines Affordable* [online]. Available from: http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/ [Accessed 28 June 2016]; Reichman, J. (2009) Compulsory licensing of patented pharmaceutical inventions: Evaluating the options. *Journal of Law, Medicines and Ethics*, 37(2), pp. 247-263. The US Trade Representative (USTR) continues to put countries on its Special 301 watch list for using TRIPS flexibilities, in stark contrast to the Doha Declaration, which was universally agreed by all WTO Members (Office of the United States Trade Representative (2016) 2016 Special 301 Report. *Office of the United States Trade Representative* [online]. Available from: https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf [Accessed 3 June 2016].

[75] United Nations General Assembly (2015) Report of the Special Rapporteur in the field of cultural rights, A/70/279, para. 90 [online]. Available from: http://www.un.org/en/ga/search/view_doc.asp?symbol=A/70/279 [Accessed 30 June 2016].

[76] Art. 7 TRIPS Agreement states that *"[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

[77] The US Pharmaceutical Research and Manufacturers of America (PhRMA) for instance argues that intellectual property protections such as patents and data protection provide the incentives that spur research and development, ensuring that companies can secure the resources for future investments in research for the innovations of tomorrow. See: PhRMA (n.d.) Intellectual property protections are vital to continuing innovation in the biopharmaceutical industry. *PhRMA* [online]. Available from: http://www.phrma.org/innovation/intellectual-property [Accessed 3 June 2016].

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[84] In the United States for instance, the average retail price increase for 622 widely used medicines was more than six times higher than the rate of general inflation in 2013. Schondelmeyer, S. and Purvis, L. (2016) Rx Price Watch Report: Trends in retail prices of prescription drugs widely used by older Americans, 2006 to 2013. *AARP Public Policy Institute* [online]. Available from: http://www.aarp.org/content/dam/aarp/ppi/2016-02/RX-Price-Watch-Trends-in-Retail-Prices-Prescription-Drugs-Widely-Used-by-Older-Americans.pdf [Accessed 15 July 2016].

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[87] Across OCED countries, pharmaceutical spending reached around US$ 800 billion in 2013, amounting to 20% of total health spending on average when pharmaceutical consumption in hospitals is added to the purchase of pharmaceutical drugs in the retail sector. See OECD (2015) Health at a Glance 2015: OECD Indicators. *OECD* [online]. Available from: http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/health-at-a-glance-2015_health_glance-2015-en [Accessed 15 July 2016].

[88] For discussion of pros and cons of voluntary licences, see Park, C., *et al.* (2012) Understanding voluntary licensing: An analysis of current practices and key provisions in antiretroviral voluntary licences. *Medicines Patent Pool*, 2012 XIX International

AIDS Conference [online]. Available from: http://www.medicinespatentpool.org/wp-content/uploads/Current-Practice-and-Key-Provisions-in-ARV-VLs.pdf [Accessed 3 June 2016]; and Amin, T. (2007) Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines?. *I-MAK* [online]. Available from: http://static1.1.sqspcdn.com/static/f/129694/1099999/1192729231567/Oxfam+-+Voluntary+Licensing+Research+IMAK+We [Accessed 6 June 2016].

[89] According to its Executive Director, by mid-2015, the MPP's work had saved the international community US$ 119.6 million through the purchase of more affordable treatments. This is equivalent to one year of first-line treatment for approximately 950,000 people. Contribution (115) from Greg Perry, Medicines Patent Pool, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/28/greg-perry [Accessed 3 June 2016].

[90] The Medicines Patent Pool (2015) The Medicines Patent Pool expands mandate to hepatitis C and tuberculosis treatment. Available from: http://www.medicinespatentpool.org/the-medicines-patent-pool-expands-mandate-to-hepatitis-c-and-tuberculosis-treatment/ [Accessed 28 July 2016].

[91] For example, Merck's voluntary licence for paediatric formulations of *raltegravir* excluded countries like Algeria, Tunisia and China, despite having similar economies and disease burdens as countries covered by the licence. See De Luca, C. (2015) Medicine patent pool – pharma philanthropy or PR?. *Expert Opinion on Therapeutic Patents*, 25(11), pp. 1223-1227.

[92] The Gilead *sofosbuvir* license excludes China, Brazil, the Philippines, Turkey, Thailand, Mexico – middle-income countries home to 38.5 million hepatitis C infections (Hill, A., *et al.* (2016) Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C. *Journal of Virus Eradication*, 2, pp. 28-31).

[93] Art. 27.1 TRIPS Agreement.

[94] UNDP (2010) Good practice guide: Improving access to treatment by utilizing public health flexibilities in the WTO TRIPS Agreement. *UNDP* [online]. Available from: http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf [Accessed 3 June 2016].

[95] 35 U.S.C. § 100(b), 101, 120 (2006). For further discussion, see Kapczynski, A., *et al.* (2012) Polymorphs and prodrugs and salts (Oh My!): An empirical analysis of "secondary" pharmaceutical patents. *PLoS ONE*, 7(12), e49470.

[96] Such as India's Section 3(d) The Patents Act 1970. In 2013, in a globally impactful, seven-year case, India's Supreme Court upheld the patent office's rejection of a patent application on Novartis's cancer drug Gleevec under 3(d) (*Novartis AG v. Union of India & Ors.* [2013] Civil Appeal Nos. 2706-2716 of 2013. (Supreme Court of India), paras. 103, 131-133, 157, 190. In 2012, Argentina amended its patentability criteria essentially rejecting all secondary patents claims

[97] The Government of India, for instance, has faced increasing pressure to change its IP law-specifically section 3d on patentability criteria. For example in 2014, the US Government classified India as a "Priority watch list country" in the US Special 301 Report, based on the inputs provided by the US industry on their perception of the level of protection provided by India to Intellectual Property. See Ministry of Commerce and Industry (2014) US opposition to section 3(D) of the Indian Patent Act, press release. *Government of India* [online]. Available from: http://pib.nic.in/newsite/PrintRelease.aspx?relid=107612 [Accessed 6 August 2016].

[98] Kapczynski, A., *et al.* (2012) Polymorphs and prodrugs and salts (Oh My!): An empirical analysis of "secondary" pharmaceutical patents. *PLoS ONE*, 7(12), e49470; Committee on Development and Intellectual Property (CDIP) (2015) Study on pharmaceutical patents in Chile (CDIP/15/INF/2) *WIPO* [online]. Available from: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_15/cdip_15_inf_2.pdf [Accessed 7 June 2016], pp. 5-6.

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[101] WIPO (2011). Patent landscape report on ritonavir. *WIPO* [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946.pdf [Accessed 3 June 2016], p. 16.

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[103] WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO and WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016], pp. 135-136.

[104] The lack of patent examination in South Africa results in a disproportionately high number of grants compared with other emerging economies (Correa, C. (2011) Pharmaceutical innovation, incremental patenting and compulsory licensing. *Centre for Interdisciplinary Studies of Industrial Property and Economics* [online]. Available from: http://idl-bnc.idrc.ca/dspace/bitstream/10625/47912/1/IDL-47912.pdf [Accessed 3 June 2016]). ICTSD, UNCTAD and WHO have also published guidelines (Correa, C. (2007) Guidelines for the examination of pharmaceutical patents: Developing a public health perspective. *WHO, ICTSD and UNCTAD* [online]. Available from: http://www.ictsd.org/sites/default/files/research/2008/06/correa_patentability20guidelines.pdf [Accessed 7 June 2016]). In 2016, UNDP published a more detailed and updated version of guidelines (Correa, C. (2016*)* Guidelines for the examination of patent applications relating to pharmaceuticals: Examining pharmaceutical patents from a public health perspective. *UNDP* [online]. Available from: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html [Accessed 28 June 2016]).

[105] Correa, C. (1999) Intellectual property rights and the use of compulsory licences: Options for developing countries. *South Centre* [online]. Available from: http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf [Accessed 3 June 2016], pp. 3-4.

[106] Lybecker, K. and Fowler, E. (2009) Compulsory licensing in Canada and Thailand: Comparing regimes to ensure legitimate use of the WTO rules. *Journal of Law, Medicine and Ethics,* 37(2), pp. 222-239.

[107] Abbas, M. (2013) Pros and cons of compulsory licensing: An analysis of arguments. *International Journal of Social Science and Humanity*, 3(3), p. 255.

[108] The government of Brazil used this strategy effectively to bring down the prices of AIDS drugs throughout the early 2000s. It also issued a CL in 2007 for efavirenz in its attempts to negotiate a price reduction (Abbott, F. and Reichman, J. (2007) The Doha round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of International Economic Law.* 10(4), pp. 950-952. Other LIMCs in Africa, Asia and Latin America have done the same to persuade originator pharmaceutical companies to invest in local production of a needed drug. The United States threatened to issue Bayer with a compulsory licence in 2001, when the government wanted to stockpile ciprofloxacin for defence against anthrax and the patent holder refused to provide significant price discounts. In response, Bayer drastically cut its price in response to the threat of a compulsory licence being issued (Reichman, J. (2009) Compulsory licensing of patented pharmaceutical inventions: Evaluating the options. *Journal of Law, Medicines and Ethics,* 37(2), p. 256.

[109] UNAIDS (2011) Doha +10, TRIPS flexibilities and access to antiretroviral therapy: Lessons from the past, opportunities for the future. Technical Brief. *UNAIDS* [online]. Available from: http://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA%2B10TRIPS_en_0.pdf [Accessed 8 August 2016], p.22.

[110] See WTO (2005) Amendment to the TRIPS Agreement, WT/L/641. Available from: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_wtl641_e.pdf [Accessed 8 August 2016].

[111] South Centre (2011) The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. Policy Brief 7. *South Centre* [online]. Available from: http://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf [Accessed 15 July 2016].

[112] Vandoren, P. and Eeckhaute, J. (2003) The WTO decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. *The Journal of World Intellectual Property,* 6(6), pp. 779-793; Dutfield, G.(2008) Delivering drugs to the poor: Will the TRIPS amendment help? *American Journal of Law and Medicine,* 34(2,3), pp. 107-124.

[113] As of the end of June 2016, 86 WTO Members had accepted the amendment of the TRIPS Agreement out of a total membership of 163 countries.

[114] For example, see African Union Commission and United Nations Industrial Development Organization (AUC-UNIDO) (2012) Pharmaceutical manufacturing plan for Africa. *UNIDO* [online]. Available from: http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf [Accessed 6 June 2016].

[115] Art. 8.2 TRIPS Agreement: "*Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.*"

[116] See: UNCTAD (2015) The role of competition in the pharmaceutical sector and its benefits for consumers. Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices, TD/RBP/CONF.8/3 Available from: http://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_en.pdf [Accessed 29 June 2016]. Contribution (181) from Duncan Matthews and Olga Gurgula. Queen Mary University, March 2016. Available from: http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/5755bda2d51cd4f6f57d96af/1465236909052/Submission+to+the+UN+HLP_on+competition++policy_final%255b1%255d.pdf [Accessed 8 August 2016].

[117] Examples include the decisions by the Competition authority of Italy to order pharmaceutical companies to grant licences to competitors for the production of an active pharmaceutical ingredient used to treat hypertrophy of the prostate in one case and the treatment of serious hospital infections in another instance. See Love, J. (2007) Recent examples of the use of compulsory licences on patents: KEI Research Note 2. *KEI* [online]. Available from: http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf [Accessed: 29 June 2016].

[118] United Nations agencies, including UNCTAD, have developed a model law on competition law, which is regularly updated: UNCTAD (2015) The model law on competition. *UNCTAD* [online]. Available from: http://unctad.org/en/Pages/DITC/CompetitionLaw/The-Model-Law-on-Competition.aspx [Accessed 7 June 2016]. And agencies like UNDP have provided expert guidance in using competition law in applying the TRIPS flexibilities: UNDP (2014) Using competition law to promote access to health technologies: A guidebook for low- and middle-income countries. *UNDP* [online]. Available from: http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html [Accessed 7 June 2016]). The European Commission in its Pharmaceutical sector inquiry in 2009 (European Commission (2008) Pharmaceutical sector inquiry: Preliminary report. *European Commission* [online]. Available from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [Accessed 7 June 2016]) and the WHO, WIPO, WTO Trilateral Study in 2012 (WHO, WIPO and WTO (2013) Promoting access to medical technologies and innovation. *WHO, WIPO, WTO* [online]. Available from: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf [Accessed 31 May 2016]) also highlighted various strategies that the biopharmaceutical industry may employ that may constitute anti-competitive behaviour.

[119] To achieve policy coherence in matters of intellectual property, trade and access to health technologies, a number of countries have established national committees comprising diverse and relevant stakeholders. Zambia, for example, created an inter-ministerial committee on IP and TRIPS chaired by the vice president of the country. This was important for two reasons: first, it ensured that a common strategic vision in the best interests of the country was prioritized over the individual priorities of each member of the committee. Secondly, it elevated decision making to the top levels of national leadership, ensuring that whatever political decisions were made could immediately filter to all the line ministries that were involved in implementation (Chilambwe, J. (2016) *Intervention by representative of the Patents and Companies Registration Agency, Zambia*. High-Level Panel Hearing. Johannesburg, South Africa. 16 March 2016).

[120] As of September 2015, PEPFAR was supporting antiretroviral treatment (ART) for nearly 9.5 million people worldwide. As of mid-2015, the Global Fund has provided HIV/AIDS treatment to 8.6 million people. See InterAction (2016) HIV/AIDS, PEPFAR and The Global Fund. *InterAction* [online]. Available from: https://www.interaction.org/choose-to-invest-2017/hivaids-pepfar-global-fund [Accessed 15 July 2016].

[121] Currently, the originator company Eli Lilly is suing the government of Canada for US$ 500 million over the invalidation of Eli Lilly's patents on Strattera and Zyprexa, which are used to treat ADHD and schizophrenia, respectively. Lilly is invoking "foreign investor privileges" granted under NAFTA, to demand compensation from governments if their policies or rulings undermine "expected future profits" (*Eli Lilly and Company v The Government of Canada)*, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (Nov. 7, 2012). Available from: http://italaw.com/sites/default/files/case-documents/italaw1172.pdf [Accessed 3 June 2016]. More at: http://www.italaw.com/cases/1625 [Accessed 3 June 2016]). The US Trade Representative (USTR) furthermore, continues to put countries on its Special 301 watch list for using TRIPS flexibilities, in stark contrast to the Doha Declaration which was universally agreed to by all WTO Members (Office of the United States Trade Representative (2016) 2016 Special 301 Report. *Office of the United States Trade Representative* [online]. Available from: https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf [Accessed 3 June 2016]).

[122] Weatherall, K. (2013) TPP – Australian section-by-section analysis of the enforcement provisions of the August leaked draft. *Sydney Law School Research Paper No. 13/84* [online]. Available from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2357259 [Accessed 21 July 2016]. See also Article 18.78, Chapter 18 (Intellectual Property), Full Text of the TPP. Available from: https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf [Accessed 18 July 2016].

[123] Contribution (72) from Sanya Reid Smith, Third World Network, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/28/third-world-network [Accessed 20 June 2016]. See also: Mercurio, B. (2006) TRIPS-Plus provisions in FTAs: Recent trends. In: Bartels, L. and Ortino, F. (eds.) *Regional trade agreements and the WTO legal system*. Oxford Scholarship [online]. Available from: https://www.researchgate.net/publication/228154939_TRIPS-Plus_Provisions_in_FTAs_Recent_Trends [Accessed 20 June 2016]. See also: Lindstrom, B. (2010) Scaling back TRIPS-Plus: An analysis of intellectual property provisions in trade agreements and implications for Asia and the Pacific. *Journal of International Law and Politics*, 42(3), pp. 917-980. See also: Lopert, R. and Gleeson, D. (2013) The high price of "free" trade: United States trade agreements and access to medicines. *The Journal of Law, Medicine and Ethics*, 41(1), pp. 119-223. See also: WHO, WIPO and WTO (2012) Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade. *WHO, WIPO and WTO* [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf [Accessed 20 June 2016]. See also: Office of the United States Trade Representative (2016) TPP full text. *USTR* [online]. Available from: https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [Accessed 18 July 2016].

[124] This is more than seven times of what the next-largest funder, the European Commission, spent. See Viergever, R. and Hendriks, T. (2015) The 10 largest public and philanthropic funders of health research in the world: What they fund and how they distribute their funds. *Health Research Policy and Systems*, 14(12).

[125] 35 United States Code 200 "*It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and non-profit organizations, including universities; to ensure that inventions made by non-profit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions; and to minimize the costs of administering policies in this area*."

[126] Prior to 1980, less than 5% of the 28,000 patents being held by federal agencies had been licensed out. See: United States General Accounting Office (1998) Report to Congressional Committees, technology transfer: Administration of the Bayh-Dole Act by research universities, GAO/RCED-98-126. *United States General Accounting Office* [online]. Available from: http://www.gao.gov/archive/1998/rc98126.pdf [Accessed 21 July 2016].

[127] Grimaldi, R., *et al*. (2011) 30 years after Bayh–Dole: Reassessing academic entrepreneurship. *Research Policy*, 40, pp. 1045-1057.

[128] Legislation similar to Bayh-Dole has been introduced in Brazil (*Innovation and Research in Science and Technology 2004* or Law No. 10.973 of 2004), China (*Law of the People's Republic of China on Scientific and Technological Progress 2007*), Denmark (*Act on Inventions at Public Research Institutions 1999*), Germany (*Arbeitnehmererfindungsgesetz* 2002, i.e. the abolition of *Hochschullehrerprivileg* or 'Professor's Privilege'), Malaysia (*The Government Circular on the Management of Intellectual*

Property Owned by the Government and the Distribution of Royalties 1999 and the *Intellectual Property Commercialisation Policy for Research and Development Projects Funded by the Government of Malaysia 2009*), Singapore (*Patents Act 1994*) and South Africa (*Intellectual Property Rights from Publicly Financed Research and Development Act 2008*).

[129] Loise, V. and Stevens, A. (2010) The Bayh-Dole Act turns 30. *Science Translational Medicine*, 2(5), p. 2.

[130] So. A., *et al*. (2008) Is Bayh-Dole good for developing countries? Lessons from the US experience. *PLoS Biology*, 6(10), e262.

[131] Boettiger, S. and Bennett, A. (2006) Bayh-Dole: If we knew then what we know now. *Nature Biotechnology*, 24, pp. 320-323.

[132] For instance, in 2001 Yale University granted Bristol-Myers Squibb an exclusive license to the antiretroviral stavudine, which BMS priced at US$ 1,600 per patient per year—out of reach for poor countries with high HIV prevalence. Under pressure from civil society, Yale and BMS extended the license to a South African generic manufacturer, which dropped the price to US$ 55 (Chen, C., *et al*. (2010) The silent epidemic of exclusive university licensing policies on compounds for neglected diseases and beyond. *PLoS Neglected Tropical Diseases*, 4(3), e570).

[133] Lee, W.H. (2015) Open access target validation is a more efficient way to accelerate drug discovery. *PLoS Biology*, 13(6), e1002164.

[134] Kesselheim, A. (2010) Using market-exclusivity incentives to promote pharmaceutical innovation. *New England Journal of Medicine*, 363, pp.1855-1862.

[135] Chokshi, D. (2006) Improving access to medicines in poor countries: The role of universities. *PLoS Medi*cines, 3(6), pp. 723-726. See also: Kapczynski, A. (2005) Addressing global health inequalities: An open licensing approach for university innovations. *Berkeley Technology Law Journal*, 20(2), pp. 1031-1114.

[136] Trouiller, P., *et al*. (2002) Drug development for neglected diseases: A deficient market and a public-health policy failure. *The Lancet*, 359, pp. 2188-2189.

[137] The Review on Antimicrobial Resistance. (2016) Tackling drug-resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government* [online]. Available from: http://amr-review.org/ [Accessed: 27 June 2016]. See also: Clift, C., *et al*. (2015) Towards a new global business model for antibiotics: Delinking revenues from sales. Report from the Chatham House Working Group on New Antibiotic Business Models. *Chatham House* [online]. Available from: https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20151009NewBusinessModelAntibioticsCliftGopinathanMorelOuttersonRottingenSo.pdf [Accessed 29 June 2016], p. vii.

[138] About 47% of the novel drugs approved in 2015 (21 of 45) were approved to treat rare or 'orphan' diseases that affect 200,000 or fewer Americans. See: US Drug and Food Administration (2016) Novel drugs summary 2015. *US Drug and Food Administration* [online]. Available from: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm [Accessed 27 June 2016].

[139] Frenk, J. and Moon, S. (2013) Governance challenges in global health. *The New England Journal of Medicine*, 368, p. 939.

[140] For a comprehensive survey of existing initiatives, see Kiddell-Monroe, R., Greenberg, A. and Basey, M. (2016) Re:Route: A map of the alternative biomedical R&D landscape. *Universities Allied for Essential Medicines (UAEM)* [online]. Available from: http://www.altreroute.com/assets/download/UAEM_Reroute_Report.pdf [Accessed 2 June 2016].

[141] The Commission's recommendations for fostering innovation and access are still relevant today. However, the focus of the Commission on low- and middle-income countries was narrower than this Panel's mandate. Commission on Intellectual Property Rights, Innovation and Public Health (2006) Public health, innovation and intellectual property rights. *WHO* [online]. Available from: http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1 [Accessed 2 June 2016].

[142] Some criticism has arisen in response to the current model of AMC as it has acted as a purchasing mechanism instead of pulling new invention from late stage development to the market at affordable price. See Médecins Sans Frontières (MSF) (n.d.) Advance market commitment. *MSF* [online]. Available from: http://www.msfaccess.org/spotlight-on/advance-market-commitment [Accessed 8 August 2016].

[143] The WIPO Re:Search consortium, for example, connects the assets and resources of pharmaceutical companies, such as compound libraries, to academic or non-profit researchers with novel ideas for product development (See: Ramamoorthi, R., Graef, K. and Dent, J. (2014) WIPO Re:Search: Accelerating anthelmintic development through cross-sector partnerships. *International Journal for Parasitology: Drugs and drug resistance*, 4(3), pp. 220-225). And a particularly prolific PDP is DNDi, established in 2003 to catalyse scientific projects to meet the needs of neglected patients. One of DNDi' s most significant releases, NECT, the first new, improved treatment for advanced state sleeping sickness in 25 years, was the result of a six-year partnership of NGOs, the WHO, governments and originator pharmaceutical companies (See: DNDi (2014) An innovative approach to R&D for neglected patients: Ten years of experience and lessons learned by DNDi. *DNDi* [online]. Available from: http://www.dndi.org/wp-content/uploads/2009/03/DNDi_Modelpaper_2013.pdf [Accessed 31 May 2016]).

[144] Data from 2014. Policy Cures (2015) Neglected disease research and development: The Ebola effect. *G-FINDER Report 2015* [online]. Available from: http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf [Accessed 2 June 2016], p. 76.

[145] Uniting to Combat NTDs (2016) The London Declaration. *Uniting to Combat NTDs* [online]. Available from: http://unitingtocombatntds.org/london-declaration [Accessed 27 June 2016].

[146] Policy Cures (2015) Neglected disease research and development: The Ebola effect. *G-FINDER Report 2015* [online]. Available from: http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf [Accessed 2 June 2016], p. 5.

[147] Policy Cures (2015) Neglected disease research and development: The Ebola effect. *G-FINDER Report 2015* [online]. Available from: http://policycures.org/downloads/Y8%20

GFINDER%20full%20report%20web.pdf [Accessed 2 June 2016], p. 69.

[148] For example, in 2016 the Japanese government replenished the Global Health Innovative Technology Fund/UNDP program with an extra US$ 130 million, adding to an earlier investment of US$ 70 million made in 2013 (see: Global Health Innovative Technology Fund, "Government of Japan announces decision to contribute US$ 130 million to GHIT Fund/UNDP replenishment," *GHIT Fund* – Press Release [online]. Available from: https://www.ghitfund.org//about/mediacenter/pressdetail/detail/164 [Accessed 2 June 2016]). Another important development is the announcement by the UK government in late 2015 that it would be establishing the £1 billion Ross fund which includes £350 million earmarked for the development of new health technologies to treat Malaria, TB, NTDs and emergent infections (see: UK Department of Health and UK Aid (2016) Ross Fund – Summary. *Department for International Development* [online]. Available from: https://www.gov.uk/government/news/the-ross-fund-combatting-the-worlds-most-serious-diseases [Accessed 3 June 2016]). The Global Health Investment Fund (GHIF) furthermore, combines investments from donor governments and the Gates Foundation with private sector expertise to form a US$ 108 million PDP investing in neglected diseases including HIV, Malaria and NTDs (see: GHIF (n.d.) An innovative response to the challenge of financing global health research and development. *GHIF* [online]. Available from: http://www.ghif.com/ [Accessed 3 June 2016]).

[149] Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance (2016). Available from: http://amr-review.org/sites/default/files/Declaration_of_Support_for_Combating_AMR_Jan_2016.pdf [Accessed 27 June. 2016].

[150] MSF, for instance, points out that even at the lowest, subsidized prices, the cost of fully vaccinating a child increased 68-fold from 2001 to 2014, "calling into question the sustainability of immunisation programmes after countries lose donor support." (See MSF (2015) The right shot: Bringing down barriers to affordable and adapted vaccines (2nd ed.). *MSF* [online]. Available from: http://cdn.doctorswithoutborders.org/sites/usa/files/attachments/the_right_shot_2nd_edition.pdf [Accessed 31 May 2016].

[151] WHO Secretariat (2016) Global action plan on antimicrobial resistance (A69/24 Add.1). *WHO 69th World Health Assembly* [online]. Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_24Add1-en.pdf [Accessed 2 June].

[152] WHO (2016) Investing in the development of new antibiotics and their conservation. *WHO* [online]. Available from: http://www.who.int/phi/implementation/consultation_imnadp/en/ [Accessed 2 June].

[153] EU Innovative Medicines Initiative (IMI) (2010) Drive-AB – Driving re-investment in R&D and responsible antibiotic use. *IMI* [online]. Available from: http://www.imi.europa.eu/content/drive-ab [Accessed 2 June].

[154] See, e.g.: The Review on Antimicrobial Resistance (2016) Tackling drug resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government* [online]. Available from: http://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf [Accessed 2 June 2016]. See also: Clift, C., *et al.* (2015) Towards a new global business model for antibiotics: Delinking revenues from sales. Report from the Chatham House Working Group on New Antibiotic Business Models. *Chatham House* [online]. Available from: https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20151009NewBusinessModelAntibioticsCliftGopinathanMorelOuttersonRottingenSo.pdf [Accessed 29 June 2016], p. 17.

[155] World Health Assembly (WHA61.21) resolution (2008) Global strategy and plan of action on public health, innovation and intellectual property. *WHO* [online]. Available from: http://apps.who.int/medicinedocs/documents/s21429en/s21429en.pdf [Accessed 15 August 2016].

[156] An open-ended meeting with Member States was recently convened at the WHO in Geneva. (See WHO (2016) Follow up to the report of the Consultative Expert Working Group on Research and Development: Financing and coordination – Report of the open-ended meeting of Member States (A69/40). Available from: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_40-en.pdf [Accessed 31 May 2016]).

[157] United Nations General Assembly (2015) Transforming our world: The 2030 Agenda for Sustainable Development, A/70/L.1. Available from: http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E [Accessed 18 July 2016], para. 48.

[158] Contribution (17) from N. Hassoun, Binghamton University, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/16/contributionn-hassoun [Accessed 8 August 2016]. See also, e.g., Contribution (4) from Laura Laughlin, Sanofi Pasteur, March 2016. Available from: http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionlaura-laughlin [Accessed 8 August 2016].

[159] WHO (n.d.) About the Global Observatory on Health R&D. *WHO* [online]. Available from: http://www.who.int/research-observatory/about/en/ [Accessed 2 June 2016].

[160] WHO (2016) Submission to the High-Level Panel on Access to Medicines. Available from: https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56e746279f7266a586c2b893/1457997352055/WHO_HLP_Submission_7Mar2016.pdf [Accessed 2 June 2016], pp. 15-16.

[161] High-Level Panel on the Global Response to Health Crises (2016) Protecting humanity from future health crises. Report of the High-Level Panel on the Global Response to Health Crises (Advance unedited copy) [online]. Available from: http://www.un.org/News/dh/infocus/HLP/2016-02-05_Final_Report_Global_Response_to_Health_Crises.pdf [Accessed 6 June 2016], p. 4. We acknowledge the important contributions of that panel, some of which overlaps the broader mandate of this one.

[162] The United States spends US$ 1 billion on such health programmes, compared with US$ 100 billion on counterterrorism. See: Yamada, T., Ogawa, V.A., and Freire, M. (2016) Policy: Security spending must cover disease outbreaks. *Nature*, 533:7601, pp. 29-31. See also: Sands, P., *et al.* (2016) The neglected dimension of global security - A framework for countering infectious-disease crises. *The New England Journal of Medicine,* 374(13), pp. 1281-1287.

[163] Pike, J., *et al.* (2014) Economic optimization of a global strategy to address the pandemic threat. *Proceedings of the National Academy of Sciences*, 111(52), pp. 18519-18523.

[164] Centers for Disease Control and Prevention (CDC) (2016) 2014 Ebola outbreak in West Africa - case counts. *CDC* [online]. Available from: http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html [Accessed 15 August 2016].

[165] Fauci, A. S., and Morens, D. M. (2016) Zika virus in the Americas—Yet another arbovirus threat. *New England Journal of Medicine,* 374(7), pp. 601-604.

[166] The efficacy of the rVSV-ZEBOV vaccine in nonhuman primates was demonstrated over 10 years ago (see Jones, S., *et al.* (2005) Live attenuated recombinant vaccine protects nonhuman primates against Ebola and Marburg viruses. *Nature Medicine*, 11(7), pp. 786-790). See also: Grady, D. (2014) Ebola vaccine, ready for test, sat on the shelf. *The New York Times* [online]. October 23, 2014. Available from: http://www.nytimes.com/2014/10/24/health/without-lucrative-market-potential-ebola-vaccine-was-shelved-for-years.html?_r=1 [Accessed 29 June 2016].

[167] Moon, S. *et al*. (2015) Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola. *The Lancet,* 386.10009, pp. 2204-2221.

[168] Centers for Disease Control and Prevention (CDC) (2016) 2014 Ebola outbreak in West Africa - case counts. *CDC* [online]. Available from: http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html [Accessed 29 June 2016].

[169] Consultative Expert Working Group on Research and Development (2012) Research and development to meet health needs in developing countries: Strengthening global financing and coordination. *WHO* [online]. Available from: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf [Accessed 2 June 2016], p. 10.

[170] See, e.g. Bloemen, S. and Hammerstein, D. (2012) Time for the EU to lead on innovation – EU policy opportunities in biomedical innovation and the promotion of public knowledge goods. *Health Action International (HAI) Europe and TACD* [online]. Available from: http://haieurope.org/wp-content/uploads/2012/04/HAI-Europe_TACD-EU-Innovation-Paper.pdf [Accessed 2 June 2016] as well as WIPO Committee on Development and Intellectual Property (CDIP) (2014) Alternatives to the patent system that are used to support R&D efforts, including both push and pull mechanisms, with a special focus on innovation-inducement prizes and open source development models, CDIP/14/INF/12. Available from: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_14/cdip_14_inf_12.pdf [Accessed 7 June 2016].

[171] The Review on Antimicrobial Resistance (2016) Tackling drug-resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government*. [online]. Available from: http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf [Accessed 28 June 2016], p. 67.

[172] The Review on Antimicrobial Resistance (2016) Tackling drug-resistant infections globally: Final report and recommendations. *Wellcome Trust and HM Government* [online]. Available from: http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf [Accessed 28 June 2016], p. 7.

[173] WHO and TDR (2016) Health Product Research and Development Fund: A proposal for financing and operation. *WHO on behalf of TDR* [online]. Available from: http://apps.who.int/iris/bitstream/10665/204522/1/9789241510295_eng.pdf?ua=1 [Accessed 27 June 2016].

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[175] Consultative Expert Working Group on Research and Development (2012) Research and development to meet health needs in developing countries: Strengthening global financing and coordination. *WHO* [online]. Available from: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf [Accessed 2 June 2016], pp. 114-120. See also: Moon, S., *et al.* (2012) Innovation and access to medicines for neglected populations: Could a treaty address a broken pharmaceutical R&D system? *PloS Medicine,* 9(5), e1001218.

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[177] United Nations (2015) Addis Ababa Action Agenda of the third international conference on financing for development. *United Nations* [online]. Available from: http://www.un.org/esa/ffd/wp-content/uploads/2015/08/AAAA_Outcome.pdf [Accessed 8 August 2016], para.69.

[178] For the purposes of this report, good governance is made up of transparency (access to information relevant to the purpose of that governance); participation of those with a stake in the governance decisions; and accountability, including access to recourse when commitments are not honoured. See Frenk, J. and Moon, S. (2013) Governance challenges in global health. *The New England Journal of Medicine,* 368(10), pp. 939-940.

[179] SDG Targets: SDG target 16.6: Develop effective, accountable and transparent institutions at all levels; 17.13: Enhance global macroeconomic stability, including through policy coordination and policy coherence; 17.14: Enhance policy coherence for sustainable development; 17.15: Respect each country's policy space and leadership to establish and implement policies for poverty eradication and sustainable development; 17.16: Enhance the global partnership for sustainable development, complemented by multi-stakeholder partnerships that mobilize and share knowledge, expertise, technology and financial resources, to support the achievement of the sustainable development goals in all countries, in particular developing countries; 17.17: Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships. See United Nations General Assembly (2015) Transforming our world: The 2030 Agenda for Sustainable Development, A/70/L.1. Available from: https://sustainabledevelopment.un.org/post2015/transformingourworld [Accessed 27 June 2016].

[180] Existing human rights accountability mechanisms can be found at national and international levels. Whereas the former

include judicial or administrative enforcement mechanisms (e.g. litigation before tribunals, national human rights commissions or parliamentary processes), the latter have more an oversight function (e.g. United Nations Commission on Human rights, Inter-American Commission on Human Rights, African Commission on Human and Peoples' Rights European Court of Human Rights, Universal Periodic Review). See also: OHCHR (2013) Who will be accountable? Human rights and the post-2015 development agenda. *OHCHR and Center for Economic and Social Rights* [online]. Available from: http://www.ohchr.org/Documents/Publications/WhoWillBeAccountable.pdf [Accessed 27 June 2016].

[181] Doha WTO Ministerial (2001) Ministerial declaration, WT/MIN(01)/DEC/1, para. 49. Available from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm#organization [Accessed 8 August 2016].

[182] UN agencies and multilaterals working on issues of health technology innovation and access include: WHO, WIPO, WTO, UNIDO, UNCTAD, UNICEF, UNHCHR, UNAIDS and UNDP.

[183] See e.g. Weiss, T. and Wilkinson, R. (eds.) (2014) International organizations and global governance. London: Routledge. Recognition of insufficient cooperation led to, e.g., the creation of the trilateral cooperation between WHO, WIPO and WTO. See: Krattiger A., *et al.* (2015) Promoting medical innovation and access, together. Trilateral Cooperation between WHO, WIPO and WTO. Global challenges brief on trilateral cooperation. *WIPO* [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/wipo_pub_gc_10.pdf [Accessed 2 June 2016].

[184] See, e.g., Gulrajani, N., Mulley, S. and Woods, N. (2005) Who needs more coordination? The United Nations and development assistance. *Journal of International Law and International Relations*, 2(1), pp. 27-39.

[185] WHO (2015) Terms of reference for the United Nations Interagency Task Force on the Prevention and Control of Noncommunicable Diseases. *WHO* [online]. Available from: http://www.who.int/nmh/ncd-task-force/un-tf.PDF?ua=1 [Accessed 2 June 2016].

[186] United Nations General Assembly Resolution adopted by the General Assembly on 25 September 2015 (2015) A/RES/70/1. Available from: https://sustainabledevelopment.un.org/post2015/transformingourworld [Accessed 18 July 2016].

[187] See: MDG Gap Task Force (2008) Millennium Development Goal 8 – Delivering on the global partnership for achieving the millennium development goals. *United Nations* [online]. Available from: http://www.un.org/millenniumgoals/pdf/MDG%20Gap%20Task%20Force%20Report%202008.pdf [Accessed 27 June 2016] and MDG Gap Task Force (2015) Millennium Development Goal 8 – Taking stock of the global partnership for development. *United Nations* [online]. Available from: http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2015/2015GAP_FULLREPORT_EN.pdf [Accessed 27 June 2016].

[188] Secretary-General of the United Nation's Commission on Information and Accountability for Women's and Children's Health (CoIA) (2011) *Keeping promises, measuring results. Every Woman Every Child* [online]. Available from: http://www.who.int/topics/millennium_development_goals/accountability_commission/Commission_Report_advance_copy.pdf?ua=1 *[Accessed 2 June 2016]*, p. 19. In 2015 the iERG was succeeded by a nine-member Independent Accountability Panel, which monitors progress on the SDGs for women's and children's health. *Every Woman Every Child* (n.d.) *Announcement of Every Woman Every Child's Independent Accountability Panel* [online]. Available from: http://everywomaneverychild.org/accountability/independent-accountability-panel [Accessed 2 June 2016].

[189] See, e.g., OECD (2007) High-Level Forum on Medicines for Neglected and Emerging Infectious Disease: Noordwijk Medicines Agenda. *OECD* [online]. Available from: https://www.oecd.org/pcd/38845838.pdf [Accessed 7 June 2016]. A national health multi-stakeholder working group and a ministerial working group were credited for improving policy coherence in Zambia, and this process is being emulated in Lesotho (see Contribution (9) from Nthabiseng Meriam Mabokang Sekokotoana, Lesotho Ministry of Law, March 2016. Accessed from: http://www.unsgaccessmeds.org/inbox/2016/2/22/contributionnthabiseng-meriam-mabokang-sekokotoana [Accessed 7 June 2016]).

[190] Tussie, D and Saguier, M. (2011) The sweep of asymmetric trade negotiations: Overview. In: Bilal, S., *et al.* (ed.) The sweep of asymmetric trade negotiations: Problems, processes and prospects. *Latin American Trade Network* [online]. Available from: http://www19.iadb.org/intal/intalcdi/PE/2011/08165.pdf [Accessed 30 June 2016], pp. 1-16.

[191] Shadow reports are submitted to the United Nations independently of government on issues such as the rights of the child or the HIV/AIDS response; they may be presented to all of the human rights treaty monitoring bodies. They may address the specific treaty articles or specifically mirror the country's common core document (CCD). Shadow reports may also be provided to the Human Rights Council for the Universal Periodic Review (UPR). See: International Women's Rights Action Watch (IWRAW) (n.d.) Shadow reporting to United Nations treaty bodies. *IWRAW* [online]. Available from: http://www1.umn.edu/humanrts/iwraw/reports.html [Accessed 27 June 2016].

[192] CIVICUS (2016) State of civil society report. *CIVICUS* [online]. Available from: http://www.civicus.org/images/documents/SOCS2016/summaries/SoCS-full-review.pdf [Accessed 18 July 2016].

[193] In the same resolution, the United Nations Human Rights Council established the United Nations Working Group on Business and Human Rights. See: United Nations General Assembly (2011) Resolution 17/4 adopted by the Human Rights Council: Human rights and transnational corporations and other business enterprises, A/HRC/RES/17/4. Available from: https://documents-dds-ny.un.org/doc/RESOLUTION/GEN/G11/144/71/PDF/G1114471.pdf?OpenElement [Accessed 18 July 2016]. See also: OHCHR (2011) Guiding principles on business and human rights: Implementing the United Nations 'Protect, Respect and Remedy Framework'. *OHCHR and United Nations* [online]. Available from: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf [Accessed 2 June 2016].

[194] See e.g. Forman, L. and MacNaughton, G. (2015) Moving theory into practice: Human rights impact assessment of

intellectual property rights in trade agreements. *Journal of Human Rights Practice*, 7(1), pp. 109-138.

[195] Office of the High Commissioner for Human Rights (OHCHR) (2011) Guiding principles on business and human rights: Implementing the United Nations 'Protect, Respect and Remedy Framework'. *OHCHR and United Nations* [online]. Available from: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf [Accessed 2 June 2016].

[196] Moon, S. (2013) Respecting the right to access to medicines: Implications of the United Nations Guiding Principles on Business and Human Rights for Pharmaceutical Companies. *Health and Human Rights Journal*, 15(1), pp. 32-43. For further discussion of the human rights responsibilities of pharmaceutical companies, see: Marks, S. (2009) Access to essential medicines as a component of the right to health, in: Clapham, A. and Robinson, M. (eds.) *Realizing the right to health.* Zurich, Switzerland: Rüfer and Rub, pp. 82-101.

[197] General Comment 14 on the ICESCR affirms that "*while only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society*"—including private businesses—"*have responsibilities regarding the realization of the right to health.*" See Committee on Economic, Social and Cultural Rights (2000) The right to the highest attainable standard of health, General Comment No. 14, E/C.12/2000/4, para. 42. Available from: http://apps.who.int/disasters/repo/13849_files/o/UN_human_rights.htm [Accessed 8 June 2016]. The Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, furthermore, reported to the General Assembly in 2008, elaborated on those responsibilities, discussing such issues as patents, clinical trials and prices (United Nations General Assembly (2008) Report of the Special Rapporteur on the Right of Everyone to the enjoyment of the highest attainable standard of physical and mental health, A/63/263. Available from: http://www.who.int/medicines/areas/human_rights/A63_263.pdf [Accessed 8 June 2016]). The United Nations Global Compact, currently signed by 8,902 companies in 166 countries, encourages corporate social responsibility regarding human rights, labour, the environment and anti-corruption efforts (see United Nations Global Compact (n.d.) Available from: https://www.unglobalcompact.org/ [Accessed 2 June 2016]). Furthermore, the United Nations Sub-Commission on the Promotion and Protection of Human Rights recognized that although states bear the primary responsibility to promote, respect and protect human rights, "*transnational corporations and other business enterprises…are also responsible for promoting and securing…human rights*". See: Sub-Commission on the Promotion and Protection of Human Rights (2003) Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights, E/CN.4/Sub.2/2003/12/Rev.2. Available from: https://documents-dds-ny.un.org/doc/UNDOC/GEN/G03/160/08/PDF/G0316008.pdf?OpenElement [Accessed 13 July 2016]. See also: OECD (2011) OECD Guidelines for Multinational Enterprises. *OECD* [online]. Available from: http://www.oecd.org/daf/inv/mne/48004323.pdf [Accessed 13 July 2016].

[198] See UN Doc. No. E/C.12/FRA/CO/4. Unofficial translation available in The Global Initiative for Economic, Social and Cultural Rights (2016) Human rights law sources: United Nations pronouncements on extra-territorial obligations. *Global Initiative for Economic, Social and Cultural Rights* Working Paper [online]. Available from: http://globalinitiative-escr.org/wp-content/uploads/2016/06/160627-Human-Rights-Law-Sources-ETOs.pdf [Accessed 19 July 2016].

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[227] The Medicines Patent Pool maintains a patent database of selected ARVs in certain low and middle income countries (See: Medicines Patent Pool Database (most recently updated in September 2015). Available from: http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/ [Accessed 31 May 2016]). India's patent office publishes lists of pharmaceutical patent applications and grants (See: Ministry of Commerce and Industry India. Controller General of Patents, Designs and Trademarks (lastly updated 2012). Available from: http://ipindia.nic.in/app_Status/granted_Patent_Pharma_01012009_31122011.xls, http://ipindia.nic.in/iponew/Patent_PharmaProduct_2005_06_2009_10.pdf, http://ipindiaonline.gov.in/workingofpatents/ [Accessed at 31 May 2016]). WHO also publishes patent landscape reports—detailed overviews of patent activity in one field—including one on vaccines (see WIPO (2012) Patent Landscape Report on Vaccines for Selected Infectious Diseases. WIPO [online]. Available from: http://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946_3.pdf [Accessed 19 July 2016]). Civil society organizations such as I-MAK have undertaken important patent landscapes of other diseases (see, e.g., Initiative for Medicines Access and Knowledge (I-MAK) (2013) Patent Landscape Report for Pegylated Interferon Alfa 2A and 2B. *I-MAK* [online]. Available from: http://static1.1.sqspcdn.com/static/f/129694/21983308/1361387069633/I-MAK+Patent+Landscape+for [Accessed 31 May 2016]. See also: See Knowledge Ecology International (KEI) (2016) Transparency of patents on medicines and other technologies. *KEI* [online]. Available from: http://keionline.org/node/2478 [Accessed 2 June 2016]. Lawyers Collective (n.d.) Drugs patent status - India. *Lawyers Collective* [online]. Available from: http://www.lawyerscollective.org/drugs-list [Accessed 6 August 2016].

ANNEX 1: COMMENTARIES

The commentaries are presented in the order that they were received.

Jorge Bermudez, Winnie Byanyima and Shiba Phurailatpam

It has been a great honour to have been a part of the UN Secretary-General's High-Level Panel on access to medicines. The Secretary-General (SG) has shown great leadership in recognizing the critical value of remedying the policy incoherence between international human rights and trade rules in the context of access to health technologies. The SG tasked us, building on previous and existing initiatives, with reviewing proposals and making recommendations to remedy this policy incoherence. This means finding ways to ensure access to existing expensive treatments and R&D for new technologies so that the world can fulfil the commitments of the Sustainable Development Goals (SDGs) to leave no one behind.

All countries have pledged to work to meet the SDGs. Furthermore, human rights including the right to life and health are universal irrespective of where a person is born--whether in a rich or poor country. Therefore, the HLP work was to address the needs of all people being denied access to health technologies including lifesaving treatments for communicable diseases, noncommunicable diseases, neglected tropical diseases and rare diseases in low-, middle- and high-income countries. This is important given the lack of R&D for many health conditions affecting or threatening to affect people all over the world and the increasingly unaffordable prices of medicines for diseases such as cancer and hepatitis C in all countries.

We acknowledge the hard work of our fellow Panel members. We also recognize the Secretariat's intensive support, as its staff worked tirelessly from the beginning. As a Panel, we have been able to agree to a number of recommendations that make some steps forward to remedy the incoherence of policies. However, we regret that the panel was not able to reach consensus to acknowledge the systemic failure of the current R&D and access system – based on intellectual property (IP) protection as embodied in the WTO's TRIPS Agreement and aggravated by free trade and investment agreements and treaties - and to elaborate proposals that could more concretely, and in the short, medium and long term, remedy the failed system.

In short, we as a Panel could have and should have been bolder. It is critical to move forward on the far more progressive and visionary proposals on financing, IP and access that seek systemic change in addition to the incremental efforts outlined in the Report. In our opinion the current recommendations are not enough, at this stage, with 15 years of the experience of using the Doha Declaration but most importantly with the evidence and testimonies presented to us by patients from different countries. The report has included encouraging recommendations on transparency and alternative systems of R&D but on the matter of access, we do not believe the recommendations should have been limited to the use of TRIPS flexibilities. The use of TRIPS flexibilities is well known, well documented and well recommended; indeed in the SDGs themselves. Therefore, the three of us have requested to add this personal commentary to the report to expand on what - in our view - should and may still be done.

The Panel received inputs from the Panel's Expert Advisory Committee and over 180 submissions and held public hearings. We have heard, followed and seen real stories of human suffering, due to lack of appropriate therapies or lack of access to existing but unaffordable technologies. Some contributions were not new ideas, and some have been included in previous reports but did not receive sufficient support to implement them. In fact, the mandate of the HLP has raised the highest expectation in people worldwide who see it as the opportunity to recommend solutions that can pave the way forwards to ensure that human rights dictate innovation and access to health technologies for all. Only this way can we truly ensure that no one is left behind by 2030 and beyond.

Yet, despite the evidence we heard from all stakeholders on the lack of adequate public investment in driving the R&D agenda and on the current problems of access to existing lifesaving treatments and health technologies under the present patent regime, the Panel has not been able to move forward on some of the bolder proposals. Below are few examples that we recommend should be taken forward:

First: We support the call for the discussion on a new IP regime for pharmaceutical products which is consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. We support the findings and recommendations of the Global Commission on HIV and the Law in this regard. It is with regret that there was lack of consensus within the Panel on examining proposals to remedy the incoherencies in the human rights and trade frameworks as they relate to the current system of IP and thus the report has no recommendations in this regard. We do not accept the assertion in the Report that any process to renegotiate TRIPS or a new IP system that recognizes the primacy of human rights, may result in the derogation of such rights. We reiterate that on this matter there was neither consensus nor any conclusion of the HLP. *We recommend that this critical recommendation should be pursued in other UN forums.*

Second: The threats of retaliation if governments use or show their intent to use TRIPS flexibilities (as the Report illustrates with Thailand and Colombia, among other cases) calls for recommendations of bold punitive actions against governments making such threats, which are missing in the report. We recommend the following:

All UN member states should, in compliance with prevailing international human rights obligations and TRIPS obligations, reaffirm their commitment to the anti-retaliation principle and sovereignty of WTO Members in complying with TRIPS as reflected in Article 1.1 of the TRIPS Agreement. Unilateral retaliation against countries using or intending to use TRIPS flexibilities should be deemed a violation of the TRIPS Agreement. We strongly urge the WTO to take immediate and appropriate punitive actions against such violations. We further call for an additional mechanism to be established at the UN Human Rights Council that should receive and investigate complaints (by UN member states, civil society, any other stakeholder or even by the HRC on its own accord) relating to the violation of human rights treaties as a result of trade retaliation (actual or threatened) where countries seek to use TRIPS flexibilities. The HRC should recommend actions to be taken within the framework of human rights treaties as well as include such matters in the Universal Periodic Reviews of UN members.

Third: Countries should be free from pressure when they use TRIPS flexibilities including in deciding and using pro-health patentability criteria. Although the report emphasizes countries' right to implement pro-health patentability criteria, it does not highlight the serious problems that they face when they do so. India is a case in point where pharmaceutical companies challenged Section 3(d) of India's patent law which restricts patents on new uses and new forms of existing medicines, unless in the case of the latter, there is a significant improvement in efficacy. Although the Indian Supreme Court upheld the strict application of this law in favour of the government, pressure from other countries continues in order to change the Indian law. We draw specific attention to the ongoing litigation filed by multiple multinational pharmaceutical companies against the strict patentability criteria and strict patent examination processes in Argentina and Brazil and call for an immediate withdrawal of these cases *and for the ceasing of all such litigation by industry against the use of TRIPS flexibilities.*

Fourth: TRIPS-plus measures in free trade agreements (FTAs) must be halted, reversed and banned. The report acknowledges the continuing limitations of policy space for government action because of TRIPS-plus measures in FTAs, which create further incoherence between human rights and IP protection. However, it needed to go further with strong and bold recommendations to address this incoherence. We recommend that TRIPS-plus measures must be immediately halted, reversed and banned. All new FTAs and those that are under negotiation should exclude TRIPS-plus measures as well as investor-state dispute settlement (ISDS) mechanisms. FTAs already signed must be revised to exclude TRIPS-plus measures and ISDS. We are alarmed at the ongoing negotiations on the Regional Comprehensive Economic Partnership Agreement which involves three key global producers of API and generic medicines (China, India and Thailand) and call on the governments in the RCEP negotiations to immediately remove all TRIPS-plus proposals and ISDS measures relating to health from the negotiations.

Fifth: Governments must be enabled to address access barriers within the current IP system through automatic licensing for essential medicines. Several submissions made detailed proposals on how to address access barriers within the present IP and trade framework, ranging from voluntary approaches to full exemption for patenting for some or all medicines. Yet, in spite of explicit references to the Doha Declaration, primarily voluntary approaches are being recommended. These voluntary approaches are problematic because they are inadequate and not sustainable, and are limited to geographic scope, among other concerns, that is defined by industry. We also need solutions that can provide all governments with options to address access barriers. We believe that the Medicine Patent Pool has a role to play but given the aforementioned limitations of voluntary mechanisms, we do not agree that the solution to the unaffordable prices is expanding the MPP to all diseases.

We recommend that medicines on national lists or on the WHO Model List for Essential Medicines should be exempted from IP protection. This would comply with the legal obligation of States to take measures aimed at the prevention, treatment and control of diseases, ensuring availability, accessibility, acceptability and quality of essential medicines as a core obligation of the right to health; and it is compliant with the TRIPS Agreement. We have repeatedly included in several comments that the UN Secretary-General should engage with the leadership of WTO to request an authoritative interpretation of Articles 27 and 30 of the TRIPS Agreement in order to allow members to exclude essential medicines from patentability. We were initially encouraged by the recommendation in the report that WTO Members adopt effectively automatic compulsory licensing for essential medicines. However, we are now seriously concerned that this recommendation for effectively automatic compulsory licensing have been removed at the last minute due to lack of consensus. **(please see later commentaries on this point).**

While the right to health imposes an immediate obligation to provide access to essential medicines, there is an obligation for the progressive realization of access to all health technologies and along with the immediate and effective use of TRIPS flexibilities by all countries, we also recommend that relevant UN forums and the WTO examine the issue of how IP constraints can be removed from all health technologies while protecting the justifiable rights of inventors.

Sixth: The waiver for Least Developed Countries (LDCs) should be extended.
We recommend that the LDCs' transitions periods be extended further than 2021 and 2033 so that the waiver stays in effect until an LDC country ceases to be in this category of countries. We recommend that all LDCs immediately review their national and regional IP regimes to ensure the full use of these transition periods.

In our view, several of these solutions should be made available in addition to those recommended in the main report.

Finally, the legal and advocacy work of civil society in ensuring the incorporation, use and protection of TRIPS

flexibilities in national and regional legal systems must be supported: The failure to recognize and support the range of successful and critical legal work undertaken by civil society groups in all countries in the actual implementation of TRIPS flexibilities, including use of competition law and patent oppositions, is a major gap in the narrative and the recommendations of the Report. This work is being done in the face of massive human and financial resources limitations and dwindling international funding. Accordingly, we call for UN agencies and other international aid agencies and donors to provide funding, possibly including through the creation of a specific fund, to support the legal and advocacy work of civil society, including the filing of patent oppositions

Moreover, we regret that there are a number of critical issues missing, misrepresented or insufficiently addressed in the report-problems include:

- The emphasis on "**Unavailability of health insurance**" as a reason for lack of access to medicines. This occurs despite numerous explanations that such language implies that insurance coverage leads to access to medicines. This is not correct given that insurance does not protect people from the high cost of medicines nor does it guarantee access to the medicines they need even in high income countries. There is strong evidence that public, social and private insurance use rationing in providing expensive medicines by, for example, allowing prescription of hepatitis C treatment only to patients with certain liver damage.
- Lack of a clear discussion on **access issues as they relate to existing new medicines to treat anti-microbial resistance (AMR)**. In this regard, the prices of new drugs where they do exist as well as delays in their registration in developing and least developed countries are also creating barriers in dealing with AMR in resource constrained settings. We note that for the new TB drugs like bedaquiline and delamanid, their pricing and availability remains a huge challenge in high TB burden countries. Two years after these two drugs have come onto the market, MSF estimates that less than 2% of those who need these treatments can access them while the so-called access pricing remains out of reach for most governments and patients (US $ 1,700 for delamanid through the Global Drug Facility and US $ 3,000 for bedaquiline in middle income countries). We draw particular attention to this dimension of AMR and call on all governments to take necessary legal actions to ensure the availability and affordability of existing treatments for patients who need them.
- Lack of clear reference to industry claims which were sometimes presented in a "factual" manner or as the opinion of the HLP. This includes claims that patents have produced the finances for R&D in medicines, or that the system has delivered the medicines that people need. We advised several times to clarify the language.

It remains a particular regret for us that the Panel's Report could not document or acknowledge much of the evidence placed before us in the testimonies of patients at the London and Johannesburg hearings. We believe those testimonies were the soul of the High-Level Panel's process. It is the brave struggles of patients and communities that demand we take full advantage of the opportunity presented by the High-Level Panel and the interest it has created among those concerned with R&D and access to health technologies, in order to move forward on issues beyond what has been agreed by consensus.

We believe our recommendations presented above are critical to ensure that all people all over the world have access to affordable health technologies they need, that no one is left behind and that no lives should ever be lost because of the price of a medicine.

Andrew Witty

Improving access to medicines for patients and citizens across the world is one of the great challenges of our time. It is an issue of great importance to me. I am proud that GSK has led the independent Access to Medicines Index on each of the four occasions it has been compiled.

Nobody would dispute the need for improvement in both innovation of healthcare technology and access to it. Everyone understands there is much to do. People are being left behind.

That said, advances in medical technologies, and new partnerships and collaborations, have led to a massive increase in life expectancy and a dramatic fall in childhood mortality in recent decades. The past 10-15 years has been a period of unprecedented progress. A diverse portfolio of new models and mechanisms for developing and delivering medicines, vaccines and other healthcare technologies - such as AMCs, PDPs, the Medicines Patent Pool, tiered pricing, and collaborations such as the pharmaceutical industry coalition on NTDs - have delivered extraordinarily fast and impressive results in the range of medicines and vaccines available and in the number of people able to access them.

Novel approaches and partnerships have led to tailored solutions, developed through consensus, to specific challenges and circumstances.

The huge achievements of the current system of healthcare innovation are often ignored or taken for granted. Equally, although many different stakeholders (particularly academia and public and philanthropic funding institutions) contribute significantly, it is often forgotten that almost all of the world's medical technology has come directly from, or with the enormous contribution of, the research-based pharmaceutical, biotechnology and medtech industries. Those contributions have been largely stimulated by incentives underpinned by intellectual property. The approaches and partnerships referenced above all operate within and alongside the IP system.

The Panel was limited both by the narrow, IP-orientated, scope of its mandate and the short time period during which it operated and as a result could only meet a few times as a Panel.

My fellow Panel Members and the Secretariat showed commitment, good intent, diligence, great respect and expertise throughout, and delivered some constructive comment and recommendations. While inevitably, well-trodden subjects such as TRIPS took up a lot of the Panel's time the Report introduces and encourages some new areas of focus. Notably the responsibility of Governments to transparently reconcile their policy choices as they affect access, the role of private sector employers in helping to protect their employees' health, and the scope to explore delinkage approaches in specific areas of market failure such as AMR.

Other recommendations suffer from a lack of rigorous testing, sometimes based on assertion rather than data/evidence, and some are vague, lacking clarity on how they will be progressed – for example, what will the development of a Code of Principles for Biomedical R&D address, and what patent rights would publicly-funded R&D be entitled to? These subjects will need much more exploration. The Panel had neither the time nor capacity to validate evidence submitted to it in these areas.

The Report makes two false or at least highly dubious implicit assumptions which are foundational to some of the narrative and recommendations:

Firstly, that the value (clinical or financial) of an innovation is clear at the time of discovery and patenting. It almost never is.

Second, that national governments will commit, and be able to raise, the very substantial funds that are required to incentivise future innovation. This especially in the context of an R&D Convention, which may explain why this idea, in its grandest form, remains stalled in the international forums where it has been discussed.

These two assumptions are important as they are used to reassure on alternate approaches to the current system, when in fact neither are likely to prove robust or be broadly deliverable.

Finally, the Report makes frequent reference to the range of factors impacting access, particularly in the many parts of the world where there is limited access even where no patents exist and prices are at generic levels. However, due to its narrow mandate and short timeline it does not analyse these other factors in depth nor offer a clear mechanism or process by which they can be addressed. Addressing global access to medicines requires a holistic approach to assess all factors impeding access and their relative importance, followed by practical and tailored solutions which build on what has been shown to work.

Specific Issues of Concern

Compulsory Licensing

I recognize that compulsory licenses can be used legally and that, where they are, fair and efficient compulsory license processes are needed. I also believe that industry and other stakeholders should not overreact to every compulsory license and treat it automatically as a 'no-go area' - they should respond on a case-by-case basis, after careful analysis of the facts.

The Panel could not agree on further evolution of this complex policy space and the Co-chairs correctly reflected this disagreement in the final Report. I fear that any element of automatic use of compulsory licenses for medicines would have significant unintended consequences. The journey from concept to finished medicine can take up to 25 years. If there is significant uncertainty about returns being available for successful, value-adding products at the end of that period, investors and therefore companies would be much less willing to invest the significant levels of funding required to discover, research and develop new medicines. Innovation would be endangered for patients around the world.

Compulsory licenses should be granted in line with the provisions of the TRIPs agreement and the Doha Declaration. They should therefore not be a routine or automatic element of a country's industrial or health policy, and should not generally be used if there are good therapeutic alternatives available at reasonable prices. If a compulsory license, or any other TRIPs flexibility, is to be pursued, it should be preceded by negotiation.

It is also important to acknowledge that the vast majority of the medicines on the WHO Essential Medicines List are not patented, and yet a third of the world's population do not have reliable access to them. For the 2013 list, there were 375 medicines on the list and only around 20 (5-6%) had patents. For the 2015 list, there were 409 medicines on it and only around 34 (8%) had patents. Few, if any, of those 34 are patented in LDCs or in many other poorer countries. Additionally, LDCs are not required to introduce patents for any medicines before the year 2033. This means that IP plays no role in the lack of access for these medicines and these countries, so IP-based ideas such as CLs are extremely unlikely to help.

The TRIPS framework provides countries with a variety of options which can be used as needed. Built on collaborative negotiation and voluntary agreements I believe most situations could be rapidly resolved if they are indeed priorities for the member state. I see no reason for countries to be forced or required to amend the current framework.

Delinkage

The Report states that "Ebola and Zika are a stark reminder of the need for delinkage". In fact the lack of treatments for these outbreaks has nothing to do with the market-driven IP model. The lack of preparedness was caused by many factors, not least of which is that these diseases were not regarded as global health priorities by the WHO or others, as the report acknowledges. There is no evidence that delinkage would have made a difference to readiness for these outbreaks.

Delinkage can play an important role in solving particular problems. In some PDPs for NTDs, it has helped to reduce the costs of development, make products more affordable, and get new products to patients faster.

Similarly, reflecting the unique set of issues around AMR, it is helpful that a new economic model delinks the volume of sales of a new antibacterial from the revenues the company receives.

Delinkage will likely not be appropriate or useful for many therapy areas. Different mechanisms are needed for different problems when they arise - a one-size fits all approach is not optimal, and is potentially damaging to innovation.

Including costs and prices as an aspect of Regulatory Approval

The Report suggests that the costs of developing a medicine should be shared with regulators who approve medicines. The regulatory approval system is based on quality, safety and efficacy and is well-established and well-proven.

Assessment of costs and price should not be part of that process. Not least because the skills of assessment are fundamentally different. Separate processes also maximize transparency of decision making.

Making use of TRIPs Flexibilities and other IP issues

The report overstates the extent of the TRIPS flexibilities. TRIPS does not permit unlimited use of CL or unlimited discretion to determine what is and is not patentable. Countries should consider making use of this framework as necessary and should not be mandated to do so.

Definition of patentability criteria

Patentability must be based on clear, rationale and predictable criteria. The Report proposes that Member States should have the right to define these criteria in the best interests of public health without in any way describing how that is to be judged. This would create complexity and unpredictability for all stakeholders involved in the innovation process.

Patents are granted at the very start of the development process when the impact of the discovery is unclear and when most discoveries are destined to fail. Further complexity in this arena will add no value and require extensive new capacity. It would be helpful to more clearly define the undesirable aspects of 'evergreening' rather than a wholesale change in patenting approach.

Conclusions

The current system is not perfect, but we must be careful about how we go about improving it. It would be wrong and irresponsible to fundamentally disrupt this model without a well-tested alternative ready to replace it. A proper assessment of the unintended negative consequences of proposed change is also crucial in such a highly interconnected policy space. Otherwise we risk undermining recent collaboration, and a loss of momentum in innovation, and as such could jeopardize access for future generations to key innovation.

Maria C. Freire

The High-Level Panel is united in its belief that every human life is valuable and that it is our duty and responsibility to ensure that advances in science and technology support this core tenet. Over the past months the HLP has heard, studied and addressed some of the concerns that have arisen from inconsistencies in policy and practice related to the human right to health and the creation, protection and distribution of health technologies. The wealth of information provided to the HLP and its deliberations demonstrate once again the need for concerted, purposeful action of all involved, including governments, academia, private companies, philanthropy, civil society and patients. The short period of time in which to fulfil the High-Level Panel's remit and its narrow mandate resulted in a report that may provide a platform for further discussion although it does not, and realistically could not, fully delve into the multiple causes for the lack of broad access to medical technologies.

Access to medicines and health technologies is predicated on their being available for use. The report stresses the imperative for medical innovation, without which no new drugs, vaccines, diagnostics, personal protective equipment and other fit-for-purpose medical technologies would exist. However, it does not explore viable new models for innovation that are implementable, financially sustainable or that tap, enhance and coalesce the expertise and know-how of the scientific community worldwide. Specifically, action is required on practical, concrete, achievable goals for medical innovation: ensuring the availability of scientific talent and medical personnel, in-depth understanding of the etiology of disease, implementation of novel trial designs and pre-approved protocols for clinical testing, coherence of disparate regulatory standards for reviewing and approving new technologies, strengthening manufacturing capacity, strategic stockpiling and prompt delivery of medical products. The report acknowledges additional myriad of factors that also limit availability and access, including tariffs, taxes, regulations and protectionist barriers, which are beyond the scope of the High-Level Panel remit. Nonetheless, such matters are critical to understanding why patients are not able to access the medicines they need, including those on the Essential Medicines List that may or may not be patent-protected, and to designing recommendations to overcome these hurdles.

Some of the recommendations proposed herein, while well-intentioned, could have unintended and undesirable consequences. Rather than improving the status quo, they may result in curtailing innovation; as a result, important positive trends to promote better access to public health technologies could stall or be reversed. Such a situation may arise from Recommendation 2.6.1 (b), which states that governments should implement national legislation, based on the provisions found in the Doha Declaration, that facilitates the issuance of compulsory licenses for legitimate public health needs, particularly with regard to essential medicines. There is no question that governments can and should make full, fair and responsible use of flexibilities under TRIPS, especially when the goal is to address the public health needs of their populations. The long-term effect of this recommendation, however, could be to prompt manufacturers to shy away from developing or producing health technologies that address public health needs and to direct R&D resources to health technologies that, while important for some sub-populations of patients, have little broad public health utility or impact. This potential dissonance should be studied in context, possibly by the independent review body proposed in Recommendation 4.3.2 (a), to ensure a robust, sustainable innovation engine that addresses public health needs.

Recommendation 3.4 (c) calls for negotiations on a binding R&D Convention, focused on public health, including neglected tropical diseases and antimicrobial resistance (AMR), that delinks the costs of research and development from end prices to promote access to good health. The HLP discussed delinking as an important potential tool for innovation and was clear that this mechanism is meant to enhance not supplant other drug development efforts. This is reflected in Recommendation 3.4 (c) where it clearly states that delinkage must complement existing mechanisms.

Without innovation, there will be no new tools for public health needs, new pandemics and AMR. There are already precious few diagnostics, vaccines and medicines that can address these menaces and limited resources to support research into the basic biology that underpins them. It would be unwise to set into motion activities or policies that further choke innovation, placing large populations at risk and contradicting the core principles under which the High-Level Panel was convened. As a society, we must continue the dialog and analysis with urgency, press for realistic, fact-based solutions and build on the momentum provided by the High-Level Panel to ensure that medicines are available and accessible for those who need them.

Ruth Okediji

The United Nations Secretary-General's High-Level Panel on Access to Medicines ("Panel") was convened to address one of the most intractable and morally compelling global issues of our time—lack of access to medicines and other health technologies. It is a challenge of immense proportions, affecting rich, middle-income and poor countries—although the effects fall disproportionately on developing and least developed countries. The Terms of Reference for the Panel explicitly identified policy incoherencies among trade, intellectual property (IP) and human rights as the prism through which to study the problem of lack of access to medicines and health technologies[1].

The Panel received a wealth of contributions[2] that underscore the complexity of the interface among these regimes and that have informed the Panel's findings and recommendations. Unfortunately, important aspects of the Panel's rich discussions—as well as practical steps that governments should consider to improve access—are not reflected in its formal recommendations.

The complex combination of laws, institutions, and firms that regulate the development and distribution of drugs and health technologies has done a great deal of good. Yet, as presently constituted, they have also resulted in significant misalignments between, on one hand, the composition and pricing of the drugs produced and distributed by pharmaceutical firms and, on the other hand, social welfare and human rights. For example, too few resources are devoted to vaccines and medicines to treat diseases common primarily in developing countries, and the prices of treatments that have been developed for those diseases are too high. Partly because of this misalignment, healthy life expectancy in low-income countries is sharply lower than in most industrialized countries. The international community has the scientific, institutional and legal capacity to reduce this inequality—and a moral obligation to do so.

It is true that an immediate goal of the IP system is to incentivize and reward innovation, but this is not its only goal. Intellectual property law is also an important tool to promote the public interest in encouraging investment in innovation which ultimately results in the societal diffusion of new technologies. How effectively the IP system accomplishes these social welfare objectives depends on a mix of factors—some related to the proper design and application of different IP laws, and others related to the regulatory and institutional environment in which IP is deployed—factors which vary across countries and disease categories. The freedom to experiment with initiatives that adapt IP rules to local contexts in light of these differences is essential to reducing gaps in access to medicines and health technologies.

With these general observations in mind, I provide below some additional context and detail regarding broad themes and supporting recommendations in the Panel's Report:

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[1] See Annex 4, Terms of Reference: The United Nations Secretary-General's High-Level Panel on Access to Medicines.

[2] The submissions to the HLP contain a wealth of information, insights and possible solutions to the challenge of lack of access to health technologies. These submissions should be catalogued and placed in a database accessible to the public. They are an invaluable source of new and promising initiatives; some of the ideas presented could precipitate formation of new partnerships and catalyze new approaches to various aspects of the global challenge of lack of innovation and access to medicines.

Recommendations to Enhance Innovation and Access to Health Technologies

The Panel discussed at length the limits of the IP system to address emerging threats to global public health, such as antimicrobial resistance, and the failure of these models to induce innovation directed at neglected diseases. I share many of the Panel's concerns, but wish to emphasize four practical tools and regulatory initiatives that governments, nongovernmental organizations and private firms can deploy to address neglected diseases—consistently with human rights, IP and trade treaties.

Coordinating Public Health Information and Responses

Collaboration in gathering and disseminating information concerning emerging public health threats, and coordination in developing initiatives to reduce gaps and redundancies in research and development. Such joint efforts could, for example, have mitigated the recent outbreak of Ebola in West Africa and ameliorate the current threat posed by the Zika virus.

Pricing Variations to Enhance Access to Health Technologies

Create an institutional and regulatory environment to facilitate voluntary pricing practices by pharmaceutical firms. For example, national governments could adjust their rules pertaining to reference pricing and to the exhaustion of patent rights in ways that would facilitate both inter- country and intra-country differential pricing of essential medicines. Such pricing should prioritize increasing the availability of drugs to the poorest victims of neglected diseases.

Similarly, foundations or NGOs could provide modest amounts of funding to induce generic firms to accept originator pharmaceutical firm offers of zero-royalty licenses for the production and distribution of patented drugs targeted for use in least developed countries. To avoid inhibiting voluntary pricing initiatives, any price variations, including price discrimination in favor of low-income countries, should not be targeted by high-income countries as a starting point for their negotiations with pharmaceutical firms.

Filling Gaps Left by Markets and Institutions - Innovation Models Focused on Delinkage

Identify appropriate areas in which the cost of producing health technologies can be separated or "delinked" from the cost to consumers. Delinkage as a supplementary organizing principle is particularly important for innovation in health technologies for neglected tropical diseases, orphan diseases and other diseases for which private markets are insufficiently capitalized or nonexistent. Governments or NGOs could use highly focused allocations of funds to help close the gaps in these markets. Such allocations might include targeted grants, prizes for developing vaccines aimed at specific diseases, advance market commitments for neglected diseases, grants to subsidize the development of new antibiotics (combined with appropriate limitations on deployment of those antibiotics in order to minimize resistance), and tax incentives.

A Regulatory Overlay on National Intellectual Property Regimes

Regulatory overlays that governments might impose on the IP system to incentivize firms to direct resources to diseases in developing countries. Such overlays have previously been used in other policy domains, for example to reduce pollution and increase automobile fuel efficiency. For health technologies, governments could consider two main candidates. First, Pigouvean taxes on pharmaceutical firms in proportion to the degree to which they contribute to the misalignments indicated above. Such taxes could nudge firms to develop R&D portfolios that more closely align with human rights and social welfare goals. Second, requiring all pharmaceutical firms to achieve, within a specified timeframe, a designated score on a "social-responsibility index." This index would be a fraction, the numerator of which would be an objective measure of the firm's contributions to public health (in the developing world); and the denominator of which would be a similarly objective measure of the firm's profits. Ideas like this give important flexibility to pharmaceutical firms that embrace social welfare objectives, enhancing opportunities for realistic "win-win" outcomes.[3]

Recommendations Regarding the TRIPS Agreement

The mandatory minimum standards in the TRIPS Agreement have proven to be especially challenging for developing and least-developed countries. A few points discussed at length by HLP, but not included in the Panel's formal recommendations, merit emphasis.

The Relationship between TRIPS and International Human Rights Law

A commitment to mitigate policy incoherence that adversely impacts innovation and access to medicines must have at its core the recognition that every country has a duty to fulfil its obligations in TRIPS and in international human rights law.[4] UN political and expert bodies have repeatedly reaffirmed that states can satisfy these dual commitments by tailoring IP protection to achieve overarching social and human rights objectives[5]. The flexibility mechanisms in TRIPS— such as subject matter exclusions, exceptions and limitations, compulsory licenses, and textual interpretations consistent with the treaty's overarching social welfare objectives—are essential for achieving compatibility between the two sets of international obligations[6]. However, precisely how these dual obligations will be given effect will not look the same across all countries and sectors, and certainly not in the area of public health. Governments thus have flexibility to achieve human rights-consistent outcomes that take account of local particularities[7].

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[3] As suggested by experts, it would be ideal if the pharmaceutical firms whose businesses would be subject to such a regulation would themselves participate actively in designing and implementing the system. Governments would (a) require transparency with respect to the financial data necessary accurately to measure each firm's profits and (b) support (financially and otherwise) an independent, unbiased consortium that would refine and apply the methodologies necessary to estimate fairly the health benefits generated by the distribution and consumption of particular drugs.

[4] For a comprehensive discussion, see Laurence R. Helfer and Graeme W. Austin, Human Rights and Intellectual Property: Mapping the Global Interface, Cambridge University Press, 2011.

Compulsory Licenses

Countries have the right to authorize and issue compulsory licenses. This right is explicitly safe- guarded in leading intellectual property and trade treaties and in national laws. High-, middle-, and low-income countries have all used compulsory licenses to accomplish important ends, including to reduce prices for patented medicines and health technologies. The TRIPS Agreement prescribes a process in Article 31 that must be followed when a WTO Member exercises this sovereign right. The 2001 Doha Declaration provides additional clarification of the flexibilities countries enjoy in determining the grounds for issuing compulsory licenses consistent with Article 31. Countries should be familiar with the various requirements for conditions in which the use of this tool is both warranted and justified in the TRIPS Agreement.[8] Statutory provisions for compulsory licenses adopted in several high income countries, and that are particularly expedient for public health needs, may offer useful examples of an accelerated process. All stakeholders must engage processes regarding the issuance of compulsory licenses effectively, fairly and legitimately. Moreover, countries are entitled to freedom from all forms of reprisal, whether from public or private sources, when exercising such rights.

Not Just Patents

The Panel's deliberations focused on patent law, and understandably so. But trademarks and copyright can exert monopolistic effects in the market that rival those associated with patents and with a far greater duration. The Report is silent on these issues, but there is much work that should be done to tackle the combined effects of different IP rights and other non-IP factors on the cost, distribution accessibility of medicines and health technologies.

Recommendations to Improve Domestic Regulatory Environments

Least-developed countries too often are treated as passive recipients of health aid or unskilled partners in deliberations about public health and access to medicines. Every country must be ensure that its policies and actions are targeted toward ensuring the right to health. Numerous factors can impede this vitally important goal. A country's failure to invest in the physical well-being of its own people, for example, is as much a violation of human rights, and is as morally objectionable, as is endemic corruption. Our collective silence about insufficient investments in national health systems, and the failure to hold governments accountable for these deficiencies, cannot be easily reconciled with the passionate demands to respect the Doha Declaration or to otherwise discipline the TRIPS Agreement.

Poor regulatory conditions in developing and least-developed countries significantly impede access to health technologies. Governments in these countries should begin *immediately* to tackle the policy, legal and administrative incoherence that exists among various government agencies and public health institutions to achieve these goals. A wide range of important tools could be put in place such as:

- Regulations to streamline domestic distribution channels for medicines and health technologies;
- Targeted customs procedures to facilitate prompt clearance of medicines and health technologies at national borders;
- Establishment of registries of medicines protected under national or regional patent laws to facilitate collective negotiations over price with pharmaceutical firms;
- Tax and other incentives to facilitate local production of medicines and other health technologies;

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[5] See, e.g., Patent policy and the human right to science and culture, Report of the Special Rapporteur in the field of cultural rights, UN Doc. A/70/279 (Aug. 4, 2015), para. 4 (prepared by Farida Shaheed) ("Well-designed patent laws and policies play a vital role in encouraging private investment in scientific research and development, making an important contribution to scientific progress and human well-being. In order for the international patent system to continue to serve its fundamental purpose of encouraging innovation and promoting dissemination and transfer of technology, the right balance is required between the rights of technology holders and the rights of technology users for the benefit of society as a whole."); Comm'n on Human Rights, Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, UN Doc. E/CN.4/Sub.2/2001/13 paras. 11-12 (June 27, 2001) (stating that "the balance between public and private interests [in Article 15 of the International Covenant on Economic Social and Cultural Rights (ICESCR) and Article 27 of the Universal Declaration of Human Rights] is one familiar to intellectual property law;" the key question "is where to strike the right balance"); Committee on Economic, Social and Cultural Rights, Statement on Human Rights and Intellectual Property, UN Doc. E/C12/2001/15 (Dec. 14, 2001) (IP "must be balanced with the right to take part in cultural life and to enjoy the benefits of scientific progress and its applications," and that "national and international intellectual property regimes must be consistent with" the obligations in the ICESCR).

[6] See, e.g., Special Rapporteur in the Field of Cultural Rights, The Right to Enjoy the Benefits of Scientific Progress and Its Applications, Human Rights Council, U.N. Doc. A/HRC/20/26 para. 59 (May 14, 2012) (prepared by Farida Shaheed) (emphasizing that TRIPS "flexibilities are important tools to ensure respect for human rights").

[7] Id. at para. 58 (emphasizing the "wide range of policy space given to States" that allow for "different standards of IP protection provided [that] the principles and substantive provisions [of human rights law] are fulfiled") (internal quotations omitted). Much can also be learned from national judicial decisions in which courts have developed a dynamic jurisprudence to discipline overreach in the patent system that draws upon international human rights law, constitutional law and other legal regimes including competition law. See, e.g., Alicia Ely Yamin And Siri Gloppen, Litigating Health Rights: Can Courts Bring More Justice to Health? Harvard University Press, 2011.

[8] Jerome H. Reichman, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, 37 Journal of Law, Medicine and Ethics, 247-263 (2009).

- Pooling resources and partnering with other countries and with foundations to invest in R&D targeting specific diseases in their regions. R&D agreements among developing countries could facilitate such an arrangement, and could be a step towards a global R&D Convention.

Conclusion

There is no single cause or solution to the persistent and burgeoning problem of lack of access to medicines and health technologies; but there must be single-mindedness in the global commitment to confront it. The Panel's recommendations respond to problems we know and face today. In considering these recommendations, care must be given not to drive innovation to sub-optimal levels or to unjustly tar all innovators with the same brush.

Developing solutions to the dual problems of lack of access to health technologies and lack of funding for health innovation is the collective responsibility of all countries and stakeholders. The convening of the High-Level Panel is yet another effort to urge the international community to be tenacious in seeking to reconcile great scientific promise and achievement with obdurate political will in support of human development. To this end, the most important collective work still lies ahead.

Jorge Bermudez and Winnie Byanyima

We acknowledge the great work of the Co-chairs and the hard work of the Secretariat to accommodate High-Level Panel members' views in the report. However, this note raises objections to the removal of a critical recommendation from the report because of lack of consensus.

This note reasserts our strong support for the vital recommendation on effectively automatic compulsory licensing for essential medicines that did not make it into the final report while also offering another, stronger recommendation that, we believe, would help countries to effectuate the use of TRIPS flexibilities in the face of the political difficulties faced when issuing compulsory licensing. Both recommendations are TRIPS compliant and legally tenable in the opinion of several legal experts. We encourage countries to examine these recommendations and amend their national or regional IP systems in keeping with these recommendations. These recommendations are critical to meeting the obligations of the right to health while allowing countries to also meet their obligations under the TRIPS Agreement.

Several submissions to the High-Level Panel made detailed proposals on how to address access barriers within the present IP and trade framework, ranging from voluntary approaches to full exemption for patenting for some or all medicines. Yet, in spite of explicit references to the Doha Declaration, primarily voluntary approaches have been recommended. These voluntary approaches are problematic because they are inadequate and not sustainable, and are limited to geographic scope that, among other concerns, is defined by industry. The High-Level Panel was tasked, in our opinion, to consider proposals for bigger, bolder action, and regrettably we have found ourselves unable to move beyond voluntary approaches and the existing WTO framework on IP in our discussions and recommendations regarding access to health technologies.

While the High-Level Panel's report emphasizes that all countries must incorporate and fully use TRIPS flexibilities, economic and political realities and serious power imbalances between developed and developing countries and between countries and the multinational pharmaceutical industry stand in the way of implementing this recommendation. Therefore, we were initially encouraged by the recommendation in the report that WTO Members adopt effectively automatic compulsory licensing for essential medicines. However, we are now constrained to record our dissent to the removal of this recommendation for effectively automatic compulsory licensing at the very last minute.

Views of several members of the Expert Advisory Group confirmed that the term "effectively automatic" is consistent with the letter and spirit of the TRIPS Agreement as long as the recommendation specified that the requirements of Article 31 were to be met. Two-thirds of the members of the High-Level Panel were also of the opinion that such a recommendation was important, timely and legally tenable. Yet, the report only refers to the views of some HLP members by stating that *"... a sizable minority of Panel Members were not, because of concerns over the potential incompatibility of such measures with the TRIPS Agreement and the unintended consequences that may result from such an approach"*. We believe that "incompatibility with TRIPS" is legally incorrect.

Moreover, we do not agree with the reference to "unintended consequences that may result from such an approach". We see this phrase as unnecessary alarm. The HLP was tasked to come up with concrete recommendations in order to remedy the policy incoherence, remove barriers and enhance possibilities to ensure access to lifesaving technologies for those in need. Therefore, we believe that this recommendation should be taken seriously by governments.

Governments should, in the interests of meeting human rights and health objectives, implement a system of compulsory licensing in national and/or regional legislation that is effectively automatic by way of its predictability and implementation provided the requirements in Article 31 of the TRIPS Agreement are adhered to. In particular, in the case of essential medicines, while Article 31(a) of the TRIPS Agreement requires that CLs should be considered on their individual merits, a legal mechanism meeting that requirement may employ identification as an essential medicine as the means through which the individual merits of a licence are determined.

In recognition of the political pressure and extensive litigation brought to bear on countries exercising their right to issue compulsory licenses, we recommend that medicines on national essential medicines lists or on the WHO Model List for Essential Medicines should be exempted from IP protection.

This would comply with the legal obligation of States to take measures aimed at the prevention, treatment and control of diseases, ensuring availability, accessibility, acceptability and quality of essential medicines as a core obligation of the right to health; and it is compliant with the TRIPS Agreement. We have repeatedly included in several comments that the UN Secretary-General should engage with the leadership of WTO to request an authoritative interpretation of Articles 27 and 30 of the TRIPS Agreement in order to allow members to exclude essential medicines from patentability.

While the right to health imposes an immediate obligation to provide access to essential medicines, there is an obligation for the progressive realization of access to all health technologies. Therefore, along with the immediate and effective use of TRIPS flexibilities by all countries, we also recommend that relevant UN forums and the WTO examine the issue of how IP constraints can be removed from all health technologies while protecting the justifiable rights of inventors.

Shiba Phurailatpam

"2033 means death to me." - Babalwa Malgas

At the outset, to Ruth Dreifuss and Festus Gontebanye Mogae the co-chairs of the High-Level Panel, my thanks and admiration at their gracious, respectful and determined handling of their unenviable task of pulling together competing interests and outlooks. To my co-panelists, my great appreciation for their insight, discussions and efforts towards reaching agreement and their patience, particularly those Panel members from whom I had a radically different outlook and assessment of proposals. To the Secretariat, a great debt of gratitude for their hard work and support throughout this process.

The final report of the High-Level Panel makes critical recommendations on new systems for research and development, on transparency and on governance. In terms of access, it also makes important recommendations for the incorporation and use of TRIPS flexibilities by all governments and for provisions in FTAs not to undermine the right to health. These recommendations are important and despite my reservations and concerns detailed below, I have signed the Report in the hope that these are taken forward.

However, our task is not complete in terms of recommendations relating to access to health technologies. The Report should have much more clearly addressed and recommended specific action on the fundamental question of systemic change, on recognising the primacy of human rights over trade and intellectual property rules and for the exploration of a new intellectual property system that prioritises human rights as recommended by the Global Commission on HIV and the Law. The recommendations on access in the report on TRIPS flexibilities, their use, on TRIPS-plus provisions, etc. should have been the starting point of our deliberations at the High-Level Panel and not the end point.

There are critical recommendations on what can and should be done on access to medicines and all health technologies that are detailed in the joint commentary by Winnie Byanyima, Jorge Bermudez and myself.

We must give governments more policy options to work within the existing system. The use of legal tools by governments to ensure affordable generic production and supply must be the rule rather than the exception. I therefore echo the commentary of my co-panelists Winnie Byanyima and Jorge Bermudez on the recommendation that countries should pursue effectively automatic licensing systems for essential medicines which found support with two-thirds of Panel members and was confirmed as legally tenably by several members of the EAG. My commentary strongly endorses that particular recommendation and draws attention to the dire situation of those in need of access to medicines at present that I regret has not been sufficiently addressed in the Report.

Over a decade into the full implementation of the TRIPS Agreement in all WTO developing country members, we are in a situation where a single company can now control the world-wide supply, price and availability of a medicine. This situation has been exacerbated by the increasing frequency of arrangements between patent holding companies and generic companies through voluntary licenses so that even countries where no patents exist or are even applied for are well within the control of patent holding companies. Voluntary licenses whether issued through the Medicines Patent Pool or outside of it are not only undermining access to medicines in middle income countries and but are also creating tensions in the use and implementation of TRIPS flexibilities. The glorious chaos caused by the announcement of Indian generic companies that they could make and supply quality, affordable ARVs across the developing world at a dollar a day is a thing of the past as we witness the new era of restricted, controlled and conditional access to patented medicines.

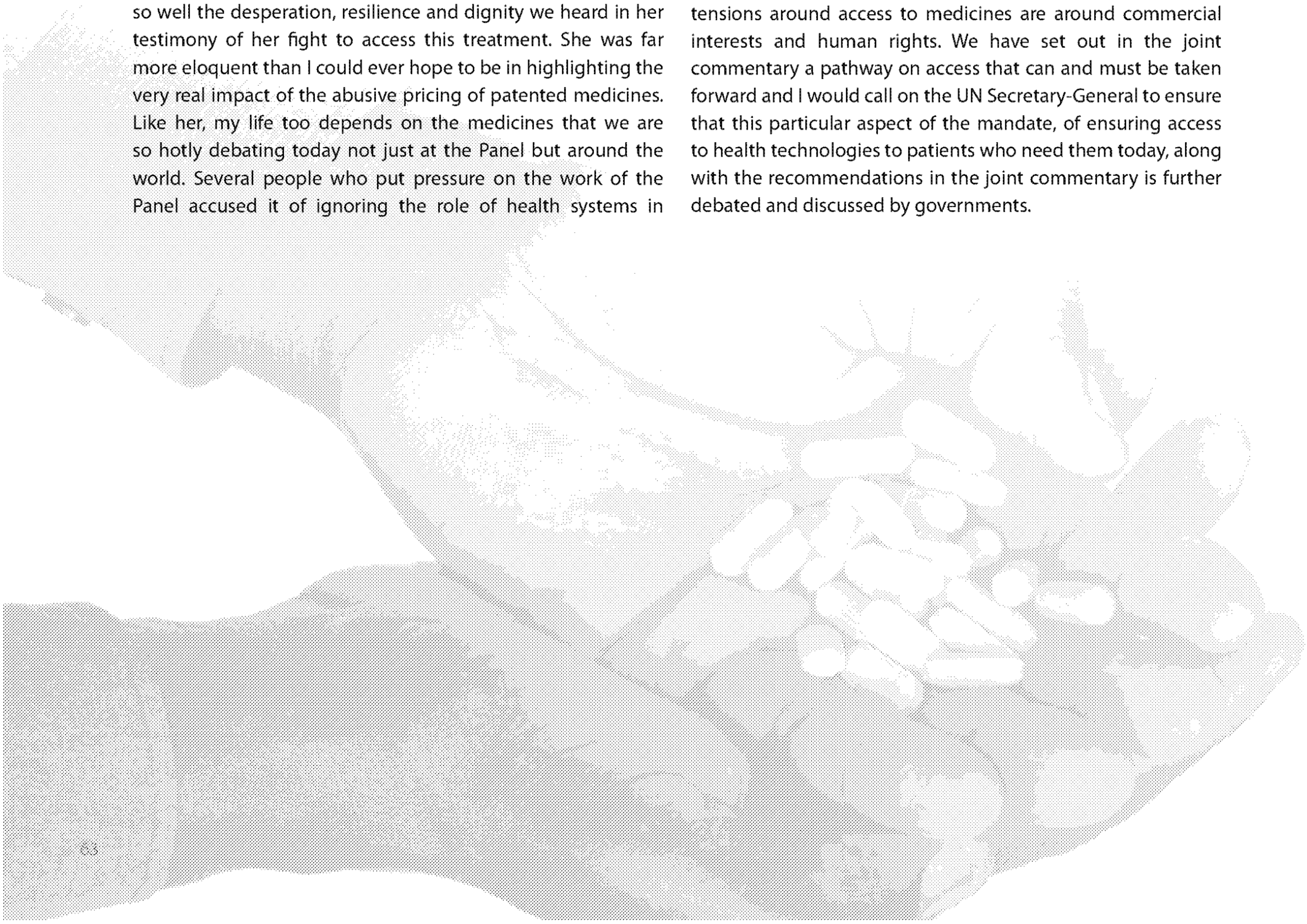
Bearing the brunt of this new era are middle-income countries that are excluded from voluntary licenses and access programmes, are facing continuous litigation and pressure in their use of TRIPS flexibilities as in the case of Brazil and Argentina and that are part of or negotiating FTAs that feature TRIPS-plus provisions. The situation of middle income countries should have received far greater attention in our Report. The prices of 2nd and 3rd line ARVs in middle-income countries are a sobering reality check on our celebrations for getting 17 million people living with HIV on treatment. "Pharmaceutical companies are selling antiretrovirals to non-African middle-income countries at prices 74–541% higher than African countries with similar gross national incomes." (Ford, Hill, et al; JIAS, 2014). Even as the GDP of countries is being used to justify violations of the right to health by the private sector, countries currently benefiting from licenses, access programmes and external funding are likely to face a challenging future as they graduate low income status.

A band of determined patients and activists stand in the way of this tightening grip of corporate power over medicines. It is my personal regret, that despite my best efforts, the critical legal work of people living with HIV, with hepatitis C, with cancer and the many, many civil society groups and public interest lawyers that work with them is not properly acknowledged or supported in this report. The legal work pursued by these groups have played a critical role in the shaping, implementation and evolution of TRIPS flexibilities as we understand them today; whether it was the competition case brought by the Treatment Action Campaign in South Africa, the DDI case in Thailand that established the standing of public interest groups in patent challenges, the patent opposition work in India, Brazil, Argentina, China, Thailand, etc., the victory of cancer groups in preventing the imposition of patent linkage in India through a litigation filed by MNCs and in successfully arguing for the strict application of Section 3(d) in the Novartis case or the successful Constitutional challenge by people living with HIV in Kenya to an anti-counterfeit legislation that threatened the import of generic medicines. The list is far longer and support for the legal work of public interest groups is critical for the successful use of TRIPS flexibilities.

The context for our work on the High-Level Panel is the 2030 deadline for the achievement of the Sustainable Development Goals. In the lives of individual patients, other dates have greater significance. 2033, Babalwa Malgas, a woman fighting breast cancer in South Africa, discovered is the date on which the patents on trastuzumab expire in South Africa. I recognized so well the desperation, resilience and dignity we heard in her testimony of her fight to access this treatment. She was far more eloquent than I could ever hope to be in highlighting the very real impact of the abusive pricing of patented medicines. Like her, my life too depends on the medicines that we are so hotly debating today not just at the Panel but around the world. Several people who put pressure on the work of the Panel accused it of ignoring the role of health systems in limiting access. In the case of patented medicines - it is my own personal experience and that of the multitude of patients in need of patented medicines - that the cascade of misery that we endure in being pushed from pillar to post, in navigating public and private healthcare systems and complicated health coverage and ultimately facing death or destitution, starts with or is certainly made far worse, by the pricing and restricted availability of those patented medicines.

What the process of the High-Level Panel has shown us is that governments will now have to take the lead in addressing access to existing medicines and health technologies. In a forum with multiple stakeholders - some who benefit from the present system and those that are losing from it - there is unlikely to be consensus on some of the most critical issues. Why would those who benefit from the current form of government regulation of intellectual property seek to change it? It is not a coincidence that articles based on leaked versions of the report focused on seeking to ensure that there was no change to the present system. There was clear evidence in the submissions and testimonies of the limitations of relying primarily on voluntary approaches and of the "punishment" meted out to countries who attempt to implement TRIPS flexibilities. It is, therefore, a disservice to me and the people who need access now to continue with the illusion that most, if not all the problems relating to access can be solved within the status quo.

I thank the UN Secretary-General for giving me the honour of being on this Panel and for recognising that the sharpest tensions around access to medicines are around commercial interests and human rights. We have set out in the joint commentary a pathway on access that can and must be taken forward and I would call on the UN Secretary-General to ensure that this particular aspect of the mandate, of ensuring access to health technologies to patients who need them today, along with the recommendations in the joint commentary is further debated and discussed by governments.



ANNEX 2: HOW THE HIGH-LEVEL PANEL REACHED ITS CONCLUSIONS

United Nations Secretary-General's High-Level Panel on Access to Medicines was comprised of 15 eminent individuals with a deep knowledge and understanding of a broad range of legal, commercial, trade, public health and human rights issues critical to promoting innovation and access to health technologies. The High-Level Panel was co-chaired by former Presidents Ruth Dreifuss of Switzerland and Festus Mogae of Botswana. The work of the High-Level Panel took place in a congenial and cooperative atmosphere with a genuine interest from Panel Members in understanding each other's point of view despite their diverse backgrounds and perspectives. While Panel Members had different points of view on occasion, they all agreed that the High-Level Panel's work was both timely and important in increasing access to health technologies for all.

The High-Level Panel was supported by an Expert Advisory Group consisting of 25 experts. Representatives were drawn from United Nations and multilateral organizations, including the World Health Organization (WHO), the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Industrial Development Organization (UNIDO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Children's Fund (UNICEF), the Office of the United Nations High Commissioner for Human Rights (OHCHR), the United Nations Special Rapporteur on the Right to Health, the Joint United Nations Programme on HIV/AIDS Secretariat (UNAIDS) and United Nations Development Programme (UNDP). Additionally, individual experts were drawn from academia, the private sector and civil society. The Expert Advisory Group was chaired by Justice Michael Kirby, who was also a member of the High-Level Panel.

The High-Level Panel cast its net far and wide, distributing its Call for Contributions to over 6,000 experts from government, civil society, academia and the private sector. The Call for Contributions requested solutions to address the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.

Briefings were held with United Nations Member States and organizations in Geneva and New York and with civil society and private sector stakeholders to raise awareness and strengthen their engagement in the work of the High-Level Panel. A total of 182 contributions were received and are available on the website of the High-Level Panel.

The High-Level Panel builds upon previous work, notably by WHO, the Human Rights Council, Special Rapporteurs on the Right to Health, the United Nations General Assembly, the trilateral cooperation between WHO, WTO and WIPO, as well as the work of numerous initiatives taken by public-private partnerships and product development partnerships. In addition to relying on existing literature, inputs from the Expert Advisory Group were provided through background papers produced at the request of the High-Level Panel and submissions by United Nations entities and international organizations, including OHCHR, UNIDO, WHO, WIPO and WTO. In March 2016, Hearings and Global Dialogues took place in London, United Kingdom, and Johannesburg, South Africa. The London Hearing and Dialogue was undertaken in partnership with The Lancet and the Centre for Commercial Law Studies, Queen Mary University of London. The Johannesburg Hearing and Dialogue was co-hosted by the Department of Health, Republic of South Africa. During the Hearings, the High-Level Panel engaged with contributors, experts and government representatives. The Global Dialogues broadened the conversation with contributors, government representatives, the private sector, academia, civil society and patient groups. The Global Dialogues were webcast and are available on the website of the High-Level Panel. A total of 1,355 people participated in Global Dialogues either in person or via webcast.

Following the Hearings and Global Dialogues, in order to develop its finding, recommendations and report, the High-Level Panel held three face to face meetings and two meetings via teleconference. Extensive email exchanges also took place, sharing reactions, comments and proposed amendments among members of the High-Level Panel, in order to reach the maximum level of consensus in finalizing the report.

This report of the High-Level Panel draws extensively upon the contributions, Hearings and Global Dialogues that were used to inform meetings of the High-Level Panel and its Expert Advisory Group. The contributions were invaluable to provide the evidence that informs the contents and recommendations of this report. The High-Level Panel would like to express profound gratitude to all those who contributed to this process.

ANNEX 3: THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

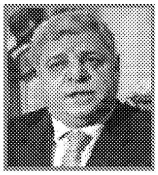
The United Nations Secretary-General's High-Level Panel on Innovation and Access to Health Technologies (High-Level Panel on Access to Medicines for short, also High-Level Panel) was comprised of 15 eminent individuals with a deep knowledge and understanding of a broad range of human rights, legal, commercial, trade and public health issues critical to promoting innovation and access to health technologies.

Co-chairs of the High-Level Panel

Festus Mogae

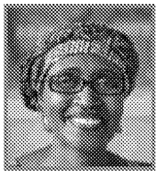
Ruth Dreifuss

Members of the High-Level Panel


Awn Al-Khasawneh

Celso Amorim

Jorge Bermudez


Winnie Byanyima

Maria C. Freire

Sakiko Fukuda-Parr

Kinga Göncz

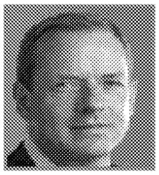
Yusuf Hamied

Michael Kirby

Malebona Precious Matsoso

Ruth Okediji

Shiba Phurailatpam


Andrew Witty

At a few meetings when members of the High-Level Panel were unable to participate in person, they were represented by nominated members of the Expert Advisory Group. In this way, Winnie Byanyima was on occasion represented by Mogha Kamal-Yanni, Yusuf Hamied was represented by Denis Broun and Andrew Witty was represented by David Rosenberg.

ANNEX 4: TERMS OF REFERENCE: THE UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

Recognizing the interdependence of health and development and in line with the recently adopted 2030 Agenda for Development and the Sustainable Development Goals, the United Nations Secretary-General has convened a High-Level Panel on Access to Medicines. The High-Level Panel and its Expert Advisory Group has the following Terms of Reference:

1. Millions of people remain left behind when it comes to accessing medicines and health technologies that can ensure their health and well-being. Failure to reduce the costs of patented medicines is resulting in millions of people being denied access to lifesaving treatments for communicable diseases like HIV, TB, Malaria and viral hepatitis, noncommunicable diseases (NCDs), NTDs and rare diseases. This failure is affecting governments and individuals in all low-, middle- and high- income countries, where budgets are being stretched to capacity by treatment costs.

2. In 2012, the Global Commission on HIV and the Law, an independent body of eminent persons tasked by the Programme Coordinating Board of the Joint United Nations Programme on HIV/AIDS (UNAIDS) with interrogating the relationship between legal responses, human rights and HIV, concluded that a growing body of international trade law is hindering the right to health of millions and that new solutions are needed to incentivize innovation and increase access to treatment.

3. Consistent with the findings and recommendations of the Global Commission on HIV and the Law, and in line with the aspirations articulated in his synthesis report on the post-2015 development agenda and the recently adopted Sustainable Development Goals, the United Nations Secretary-General Ban Ki-moon convening a High-Level Panel on innovation and access to health technologies. The overall scope of the High-Level Panel is to review and assess proposals and recommend solutions to remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies that is impeding access and the right to health for millions.

4. The High-Level Panel comprises of 15 eminent and respected individuals with expert knowledge and understanding of the broad range of trade, public health, human rights and legal issues associated with innovation of and access to health technologies. Panel members include innovators, leaders of the pharmaceutical industry, public health, human rights and international law experts, civil society and government officials.

5. The work of the High-Level Panel builds upon previous and existing initiatives, notably by the World Health Organization (WHO); these include resolutions of the World Health Assembly, work of the Human Rights Council and various Special Rapporteurs on the Right to Health and the United Nations General Assembly that have aimed to achieve a better balance of issues of intellectual property, human rights and increased access to health technologies.

6. The High-Level Panel will solicit and assess proposals, based on objective criteria, for solutions which remedy the policy incoherence between international trade rules and international human rights law. The Panel will conclude its work with a report including evidence-based and implementable recommendations that aim to achieve a better balance of human rights, public health, international trade and sustainable development objectives of United Nations Member States in the context of expanding access to health technologies. More specifically, the High-Level Panel will:

   6.1 The High-Level Panel will review and assess proposals for their potential to improve health technologies innovation and access and make recommendations that:
      a) remedy the policy incoherence between international human rights law and trade rules in the context of access to health technologies; and
      b) achieve a better balance of the justifiable rights of inventors, the right to health and sustainable development.

   6.2 Hold public hearings that facilitate multi-stakeholder dialogues involving technical experts, patient groups, civil society, governments and industry – to broaden the consultation on the proposals.

   6.3 Rely on existing materials in the public domain and request additional research on issues relevant to its enquiry.

   6.4 Make evidence-based and actionable recommendations to the Secretary-General and other relevant stakeholders on remedying the policy incoherence between international human rights law and trade rules in the context of access to health technologies.

   6.5 Serve as a platform for mobilizing stakeholders on the issues examined by the High-Level Panel and contribute to discussions in other relevant forums, including the High-Level Meeting on HIV/AIDS in 2016.

7. The work of the Panel is supported by an Expert Advisory Group assembled to provide technical support to the High-Level Panel. The High-Level Panel and its Expert Advisory Group is supported by a Secretariat based at the United Nations Development Programme in New York. The Secretariat will also work with the Secretariat of UNAIDS.

8. The Expert Advisory Group comprises of experts drawn from the public and private sector, academia, professional and civil society organizations, including people living with HIV, serving in their private capacity. It includes senior technical staff from relevant United Nations and international organizations, including WHO, the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Industrial Development Organization (UNIDO), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Children's Fund (UNICEF), the Office of the United Nations High Commissioner for Human Rights (OHCHR), the United Nations Special Rapporteur on the Right to Health, the UNAIDS Secretariat and UNDP. More specifically, the Expert Advisory Panel will:
   - Review and provide inputs into the draft technical documents prepared for consideration by the High-Level Panel, including the final report.
   - Provide inputs in assessing proposals received for review by the High-Level Panel.
   - Participate in, provide technical support and interact with the High-Level Panel during the multi-stakeholder public hearings to review and discuss the shortlisted proposals.
   - Provide other inputs as requested by the High-Level Panel.

9. The Panel will provide periodic progress reports and submit its final report to the Secretary-General by June 2016. The Secretary-General will make the report available to the General Assembly and undertake further action as appropriate.

ANNEX 5: THE EXPERT ADVISORY GROUP

Chairperson Michael Kirby	
Institutional Representatives	
Organisation	**Representative**
OHCHR	Lynn Gentile
UNCTAD	Christoph Spennemann
UNICEF	Francisco Blanco
UNIDO	Alastair West
WHO	Nata Menabde
WIPO	Thomas Bombelles
WTO	Antony Taubman
United Nations Special Rapporteur on the Right to Health	Dainius Pūras
Individual Representatives	
Frederick M. Abbott	Manica Balasegaram
Denis Broun	Carlos Correa
Maria Lorena Di Giano	Richard Elliott
Dominique Foray	Renuka Gadde
Anand Grover	Atsuko Hirooka
Mohga Kamal-Yanni	Suresh Kumar
Suerie Moon	David Rosenberg
Susan Sell	Anthony So
Paul Stoffels	

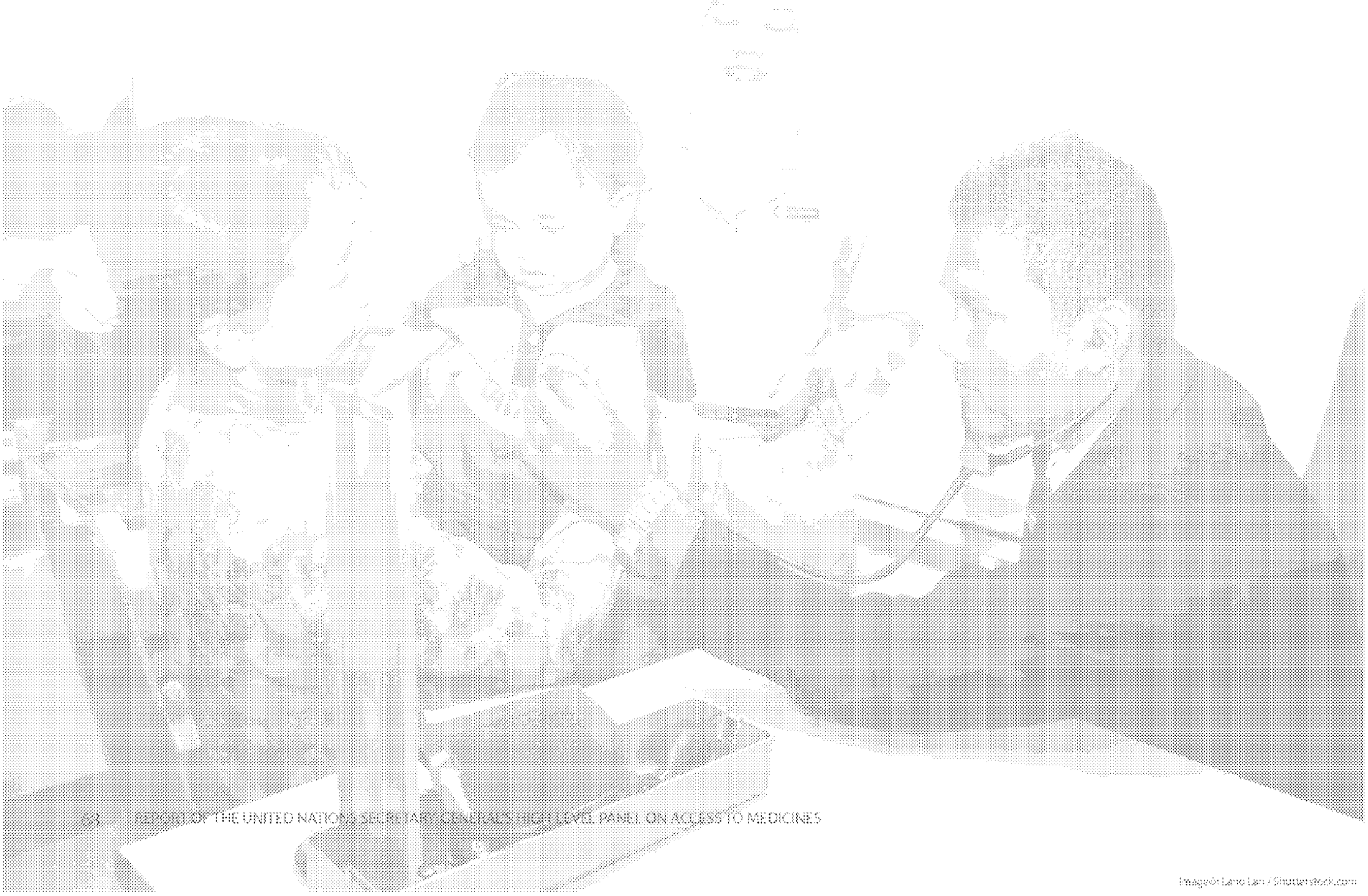


Image © Lano Lan / Shutterstock.com

UNITED NATIONS SECRETARY GENERAL'S
HIGH-LEVEL
PANEL ON ACCESS
TO MEDICINES

www.unsgaccessmeds.org

From: Schulke, Hilda (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=SCHULKEH]
Sent: 11/4/2016 2:08:33 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: CONFIRMED | FW: Mtg w Kathy Hudson (Re: Meeting Request with Secretary Burwell) | Monday, November 7, at 12:00 PM

Dr. Rohrbaugh:

Per the email below, I have confirmed this meeting for Monday, November 7, from 12:00 PM to 12:45 PM.

Thank you,

-Hilda

From: Schulke, Hilda (NIH/OD) [E]
Sent: Thursday, November 03, 2016 1:12 PM
To: Paul Davis <pdavis@keionline.org>
Cc: James Packard Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Zack Struver <zack.struver@keionline.org>
Subject: RE: Mtg w Kathy Hudson (Re: Meeting Request with Secretary Burwell)

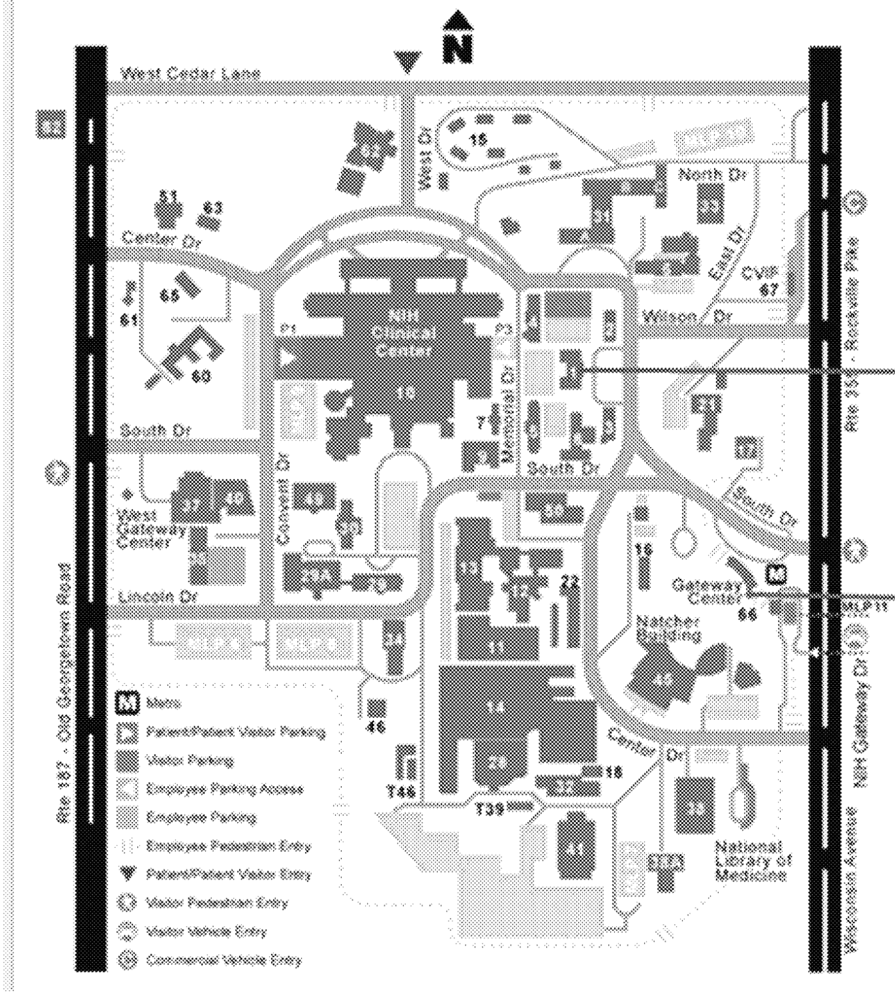
Mr. Davis:

This e-mail serves as a confirmation of the subject meeting. Please see details below.

DATE:	Monday, November 7, 2016
TIME:	From 12:00 PM to 12:45 PM
LOCATION/DIAL-IN INFO:	National Institutes of Health Building 1, Room 116 Dial-in b6 | PC: b6
TOPIC:	Xtandi
PARTICIPANTS:	For KEI: 1. Paul Davis (Via phone) 2. James Love 3. Andrew Goldman 4. Zack Struver For NIH: 1. Kathy Hudson 2. Mark Rohrbaugh 3. Rebecca Baker

The meeting will be held on the NIH Campus in Building 1, Room 116. We encourage visitors to use public transportation, as parking is limited on Campus. The Metrorail subway system has a convenient stop (Medical Center/Red Line) on the NIH Campus.

Please allow plenty of time to get through our security (**Gateway Center**.) You will need at least one form of photo identification and should be prepared to have your personal belongings screened by our security. In addition, visitors may be asked to pass metal detection tests. A map of the campus is available from the NIH website: http://www.nih.gov/about/visitor/index.htm. If you encounter any problem entering the NIH, please don't hesitate to contact our office at 301-496-1455.



Our Office is located in Building 1, Room

The Gateway Center is conveniently located across the exit of the Medical Center Metro Station.

Thank you,

Hilda

From: Paul Davis [mailto:pdavis@keionline.org]
Sent: Thursday, November 03, 2016 11:05 AM
To: Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov>
Cc: James Packard Love <james.love@keionline.org>; Andrew S. Goldman <andrew.goldman@keionline.org>; Zack Struver <zack.struver@keionline.org>
Subject: Mtg w Kathy Hudson (Re: Meeting Request with Secretary Burwell)

Thank you for getting back to us.

Of those dates, only Monday the 7th works for us.

James Love, Andrew Goldman and Zack Struver will attend in-person, and are CC'd.

I'd also be grateful if you can set up a speaker phone option. I am out of town that day and will need to call in.

What is the address of your office?

Thank you.

Paul
—
Paul Davis • pdavis@keionline.org
Knowledge Ecology Int'l
+1 202 817 0129
Skype/IM: pdavisx

> On Nov 3, 2016, at 8:13 AM, Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov> wrote:
>
> Good morning Mr. Davis:
>
> We received your voice message from Monday. Unfortunately, Dr. Hudson's calendar is almost booked through this year; therefore, we can only offer 45-min blocks of time. Please see her availability below.
>
> - Monday, November 7, from 12:00 PM to 12:45 PM
> - Wednesday, November 16, from 4:00 PM to 4:45 PM
>
> Please let us know if these times work for your team. Also, provide a list of participants on your side.
>
> Thank you,
>
> -Hilda
>
> **From:** Paul Davis [mailto:pdavis@keionline.org]
> **Sent:** Monday, October 31, 2016 12:04 PM
> **To:** Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov>
> **Subject:** Re: Meeting Request with Secretary Burwell
>
> How's it looking for this week? Preferable on or before the 3rd?
>
> Thank you.
> —
> Paul Davis • pdavis@keionline.org
> Knowledge Ecology Int'l
> +1 202 817 0129
> Skype/IM: pdavisx
>
>> On Oct 26, 2016, at 3:54 PM, Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov> wrote:
>>
>> Thank you! I'll get back to you with options soon.
>>
>> **From:** Paul Davis [mailto:pdavis@keionline.org]
>> **Sent:** Wednesday, October 26, 2016 3:51 PM
>> **To:** Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov>
>> **Subject:** Re: Meeting Request with Secretary Burwell
>>
>> An hour would be great, thank you. 90 mins if we imagine getting into legal details—but i think 60 should be fine.

Are you in Bethesda? We can meet in your office, unless Dr. Hudson would prefer to join us here in Dupont Circle.

Thank you

—

Paul Davis • pdavis@keionline.org
Knowledge Ecology Int'l
+1 202 817 0129
Skype/IM: pdavisx

> On Oct 26, 2016, at 3:47 PM, Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov> wrote:
>
> Dear Mr. Davis,
>
> How much time will you need for this meeting, and where it will be held?
>
> Thank you,
>
> Hilda
>
> <image001.png>
>
> HILDA SCHULKE | Executive Assistant
> Office of the Dep Director for Science,
> Outreach, and Policy
> NATIONAL INSTITUTES OF HEALTH
> Voice: 301-496-1455 | Fax: 301-402-2700
> E-mail: Schulkeh@od.nih.gov
>
> *Confidentiality Statement: This email message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized use, disclosure, or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and delete from your mailbox or any other storage devices.*
>
> **From:** Paul Davis [mailto:pdavis@keionline.org]
> **Sent:** Wednesday, October 26, 2016 3:33 PM
> **To:** Waitekus, Crystal (OS/IOS) <Crystal.Waitekus@hhs.gov>
> **Cc:** Hudson, Kathy (NIH/OD) [E] <Kathy.Hudson@nih.gov>; Schulke, Hilda (NIH/OD) [E] <schulkeh@od.nih.gov>
> **Subject:** Re: Meeting Request with Secretary Burwell
>
> Thank you for moving this request along.
>
> Dr. Hudson, what is your availability the week of the 31st?
>
> Look forward to connecting and moving this forward.

I'm attaching the recent correspondence thus far between 57 NGOs, HHS, letters from Biolyse, KEI and NIH.

There is more to be found here: http://keionline.org/xtandi
And here: "The Next President Can Lower Drug Prices with the Stroke of a Pen":http://washingtonmonthly.com/magazine/novemberdecember-2016/just-the-medicine/

Paul
—
Paul Davis • pdavis@keionline.org
Knowledge Ecology Int'l
+1 202 817 0129
Skype/IM: pdavisx

> On Oct 26, 2016, at 2:41 PM, Waitekus, Crystal (OS/IOS) <Crystal.Waitekus@hhs.gov> wrote:
>
> Mr. Davis:
>
> Thank you for the request to meet with Secretary Burwell about exporting Xtandi. Unfortunately, her schedule is such that she is not able to accommodate the meeting and must send her regrets.
>
> She has asked Dr. Kathy Hudson, the Deputy Director for Science Outreach and Policy at the National Institutes of Health, to meet with you in her stead. Hilda Schulkeh from her office is copied on this email and you are welcome to follow-up with her to schedule an appointment.
>
> It is also my understanding that you have a meeting with the HHS Office of Global Affairs next Tuesday, November 1.
>
> We sincerely appreciate your passion and dedication to this critical issue.
>
> All the best,
>
> Crystal Waitekus
> Deputy Scheduler to the Secretary
> U.S. Department of Health and Human Services

From: Bleimund, Emily (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=BLEIMUND.EMILY.OS]
Sent: 10/5/2016 9:29:41 PM
To: Adeniyi-Jones, Samuel (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=SAJones]; Barber, Daniel (OS/IEA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5d0c6b15d8d34785a34777e862e1e044-Barber, Daniel (OS)]; Baresch, Virginia (HHS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=286774b0313b48b88f0d0d9840b2c61c-Baresch, Virginia (O]; Bleimund, Emily (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Bleimund.Emily.OS]; Brown, Brishailah (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=66ffcdccc72c4f1b8169aba6c25833bf-Brown, Brishailah (O]; Burris, Hannah (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Hannah.Burris.os]; Carlton, Blake (OS/OGA) [Blake.Carlton@hhs.gov]; Carson, Tracy (HHS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=70870fc56eba46a59ce50b88bf355266-Carson, Tracy L (OS)]; Chadwick, Christopher (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Christopher.Chadwick.OS]; Chai, Shuen (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Shuen.Chai.os]; Clarke, Elana (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=EClark1]; Colin Mciff [McIffCL@state.gov]; Copeland, Evelyn (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12c26f6d01db4f4eaff88ef3ec7b0419-Copeland, Evelyn (OS]; Danelski, Ann (HHS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8b7530eef60b49b48451a38c7ea32511-Danelski, Ann (OS)]; Darr, Charles (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Charles.Darr.os]; Demby, Austin (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Austin.Demby.OS]; Diaz, Xochitl (HHS/OS/OGA) [Xochitl.Diaz@hhs.gov]; Dubois, Amy (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Amy.Dubois.os]; Eckles, Jacob (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Jacob.Eckles.os]; Eckstein, Erin (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Erin.Eckstein.OS]; Elvander, Erika (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Erika.Elvander.os]; Fernandez, Jose (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=JFernand]; Filpi, Lynn (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Filpi, Lynn (OS)ee2]; Forsyth, Andrew (HHS/OASH) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Andrew.Forsyth.OS]; Garner, Cevina (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A181cac3df594628a4851d02590d3989-Garner, Cevina E (OS]; Gibson, Roxanne (HHS/OGA) [/O=NIH/OU=NIHHUB/cn=HHSOS Proxy List/cn=Roxanne.Gibson]; Greene, Nicky (HHS/OS/OGA) [/O=NIH/OU=NIHHUB/cn=HHSOS Proxy List/cn=Nicky.Greene]; Hoffman, Linda M (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Hoffman, Linda M (OS)96a]; Jeada, Monica (OS/OGA) (CTR) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Afb26148fbc340ae851a6eb15ea7e35a-Jeada, Monica M (OS)]; Johns, Matthew (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Johns, Matthew LT (OS)5ac]; Kampf, Katie H. (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Katie.Stein.OS]; Kerr, Lawrence (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=48579d6ff7004abdb0e014b49c5aba80-Kerr, Lawrence (OS)]; Kimbrel, Alicia (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Alicia.Kimbrel.os]; Knotts, Ashley (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=ashley.knotts.os]; Kolker, Jimmy (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Jimmy.Kolker.os]; Koo, Han (OS/OGA) (CTR) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A42e17332a674c57b0b2b18711d3c775-Koo, Han J (OS)]; Lamourelle, Gabrielle (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Gabrie.Lamourelle.OS]; Levine, Maya (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=maya.levine.os]; Lim, Matt (STATE.GOV) [limml@state.gov]; Lim, Matthew (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Matthew.Lim.os]; Livinski, Alicia (NIH/OD/ORS) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=livinska]; Locus, Tiffany (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Locus, Tiffany1 (OS)38e]; Mamacos, Peter (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Peter.Mamacos.OS]; Martin, Julia (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5e6781fb8f0c4d5ab729100a9f16bbd6-Martin, Julia (OS)]; Matthews, Karen (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Cc63467b39324406a3a268a4a3c0b91d-Matthews, Karen L (O]; Mcconnell, Michelle (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A35a4adef99c4f78aad18ba82d8e8aab-Mcconnell, Michelle]; McKean, Maeve (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Maeve.McKean.OS]; Mikus, Kristie (HHS) [MikusKF@state.gov]; Newland, Matthew (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Matthew.Newland.OS]; O'Donnell, Allison (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Allison.O'Donnell.OS]; Olivo, Jacob (OS/OGA) (CTR) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=JACOB.OLIVO.OS]; Olsen, Laura (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Laura.Olsen.OS]; Park, Jin (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Jin.Park.os1]; Parrish-Fuentes, Adrienne (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E9741379a4ec40e38d6f7441f7dcedbc-Parrish-Fuentes, Adr]; PerezRivera, Diana (HHS/OS/OGA) [/O=NIH/OU=NIHHUB/cn=HHSOS Proxy List/cn=Diana.Perez-Rivera]; Peters, Kenisha (HHS/OS/OGA) (CTR) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Peters, Kenisha M (OS)4dd]; Quintana, Paula (HHS/OS/OGA) (CTR) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=paula.quintana.os]; Rabadan-Diehl, Cristina (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Cristina.Rabadan-Diehl.OS]; Rettmann, Brian (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Brian.Rettmann.os]; Schaeffer, Alison (HHS/OS/OGA) (CTR) [Alison.Schaeffer@hhs.gov]; Schmeissner, Peter (HHS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Schmeissner, Peter1 (OS)696]; Shaffer, Douglas (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=678fe18a60714097aa5fa9d2b14ada48-Shaffer, Douglas N (]; Shastri, Anjali (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3975e949cd3e49fd86ffe6764de86837-Shastri, Anjali (OS)]; Sircar, Neiloy (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0a0a0585301847cd929cfd468ca56f8c-Sircar, Neiloy (OS)]; Smith, Steven (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Steven.Smith.OS]; Snyder, Anne (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Anne.Berlow.os]; Sorenson, Noila (OS/OGA) (CTR) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Sorenson, Noila (OS)f70]; Stewart, Jessica L. (HHS/OS/OGA) [Jessica.Stewart@hhs.gov]; Stith, April (HHS/OS/OGA) [April.Stith@hhs.gov]; Sullivan, Lisa (HHS/OS/OGA) [Lisa.Sullivan@hhs.gov]; Swammy, JR (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=JSwammy]; Thomas, Jasmine (OS/OGA) (CTR) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8b5793153e0d42ce8643bfa45169feab-Thomas, Jasmine (OS)]; Torres, Abraham (HHS/OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8c6f2f58fb8f4c3fb8fc14eb76dd7fe7-Torres, Abraham (OS)]; Torres, Carmen-Rosa (HHS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=CTorres]; Velasco, Jose (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=jose.velasco.os]; Wagner, Lisa (OS/OGA) [/O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Wagner, Lisa2 (OS)89a]; Watts, Heather (OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Heather.Watts.os]; Watts, Diane (STATE.GOV) [wattsdh@state.gov]; Willis, Heber (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Heber.Willis.OS]; Wolfe, Mitchell (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Mitchell.Wolfe.OS]; Wong, Holly (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Holly.Wong.OS]; Wood, Rachel (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Rachel.Wood.OS]; Yu, Anne (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Anne.Yu.OS]; Yuan, Elizabeth (HHS/OS/OGA) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Elizabeth.Yuan.OS1]; Horowitz, David (HHS/OGC) [/O=NIH/OU=NIHHUB/cn=FDA Proxy List/cn=SMTP:david.horowitz@fda.gov]; Abdoo, Mark (FDA/OC) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=Mark.Abdoo.fda]; Callahan, Julie (FDA/OC) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=julie.callahan]; Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]; Hammersla, Ann (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=hammerslaa]; Berkley, Dale (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=BERKLEYD]; Valdez, Mary Lou (FDA/OC) [/O=NIH/OU=NIHEXCHANGE/cn=Recipients/cn=marylou.valdezOC]

CC: alboaz@law.gwu.edu
Subject: Background paper on the Bayh-Dole Act and march-in rights
Attachments: Bayh-Dole Act Final Oct 2016.docx

Dear colleagues,

Please see attached for your interest a background paper on “The Bayh-Dole Act and March-in Rights” that originated from the work of the summer intern for the OGA Trade & Health team, Alexis Boaz, a law student at GW. We hope this paper will help to inform you on what continues to be a repeated topic of conversation in global discussions on access to medicines. We welcome your feedback and comments and plan for this to be a living document that we will keep updated over time. Please feel free to forward to other colleagues but please limit to internal HHS distribution only.

Cheers,

Emily Bleimund

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From: Silverthorn, Courtney (Fed) [courtney.silverthorn@nist.gov]
Sent: 3/8/2019 6:07:19 PM
To: Zielinski, Paul R. (Fed) [paul.zielinski@nist.gov]; Mojdeh.Bahar@ARS.USDA.GOV; Lesley.Blancas@HQ.DHS.GOV; lisa.kilday@sol.doi.gov; daniel.p.lockney@nasa.gov; santiago.navarro@dot.gov; b6 @mail.mil; Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]; Shieh, Jennifer C. EOP/OSTP [Jennifer.C.Shieh@ostp.eop.gov]; Krieger, Carmen [krieger.carmen@epa.gov]; Allen, Susan (Billheimer) [Susan.Allen@USPTO.GOV]; 'Reddy, Kalpana' [Kalpana.Reddy3@va.gov]; Clara.Asmail@hq.doe.gov
Subject: RE: Documents for interagency small group discussions
Attachments: Copy of Green Paper Comments - Deliberative (Do not distribute).zip; Copy of Green Book Feedback breakdown - Deliberative (Do not distribute).xlsx

Hello everyone! Thank you for attending the small group discussions this week. We've received clearance to distribute the public (non-government) feedback on the draft Green Paper. Please see attached a zip file containing 29 responses, as well as the color-coded analysis spreadsheet that will assist you in locating specific comments on a particular finding. (The Agency/Federal Lab response rows have been retained to preserve the overall counts but the identifying information has been removed.)

These documents should be treated as deliberative/pre-decisional and should not be shared outside of your agency. In the event of a FOIA request related to these documents please refer the requestor back to NIST.

Thanks,
Courtney

Courtney Silverthorn, Ph.D.
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From: Silverthorn, Courtney (Fed)
Sent: Friday, March 1, 2019 3:42 PM
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Subject: Documents for interagency small group discussions
Importance: High

Hello everyone! Please see attached for our small group IAWGTT discussions next week. (If you have not already RSVP'd for either Monday or Thursday at 9am please do so ASAP!)

- Revised Green Paper draft based on public and agency feedback from 12/6/18 to 2/5/19 (redline and clean versions attached).
- Table of findings (included in paper but pulled out as a stand-alone document for your convenience)

The major changes from the 12/6 version are quickly summarized below; we will discuss in more detail in our walk-throughs next week.

- Based on OMB input, all Actions have been renamed as Findings
- Text added to explain process any Findings would need to undergo to be implemented
- No legislative changes to BD (the idea of limited software copyright has been shifted over to Stevenson-Wydler)
- No action on expanding the U.S. Manufacturing requirement at this time; more data will be needed from agencies to demonstrate scope and potential impacts
- No action on Trade Secrets, only addressing CRADA proprietary information
- Clarifications to emphasize flexibility over uniformity

Looking forward to further discussion. The documents will be distributed to the full IAWGTT and L2M groups on Monday afternoon.

Thanks,
Courtney

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Creating Communities of
Innovation
ASSOCIATION OF UNIVERSITY RESEARCH PARKS

January 4, 2019

Dr. Walter G. Copan
Under Secretary of Commerce for Standards and Technology
and Director of NIST
Gaithersburg, Maryland 20899

Dear Dr. Copan:

On behalf of the Association of University Research Parks (AURP), we would like to thank you and your team at NIST for producing the NIST 'Green Paper' *Return on Investment Initiative for Unleashing American Innovation.*

AURP represents over 200 research parks in the U.S. As you may know, the world's first research park was started at Stanford University in the late 1950's, and building research parks and communities of innovation from federal research funding is a mission for many communities across the U.S.

AURP previously submitted testimony to NIST, and we are pleased to see many of these comments reflected in the Green Paper, and we would like to take this opportunity to re-emphasize several points that are highlighted in the paper. A number of these ideas were contained in the AURP White Papers: the *Power of Place* and the *Power of Place 2.0: the Power of Innovation,* both available at www.aurp.net/power-of-place.

Flexibility in Use of Federal R and D Funds Towards Commercialization Goals:

We continue to be interested in new flexible approaches for recipients of federal funds towards commercialization goals, which can help feed new companies to university research parks. These reforms include matters such as ability of researchers to employ federal funds towards patent costs and removing restrictions on intellectual property negotiations where corporate funded research is performed in facilities funded with tax-exempt bonds at universities.

Federal Researcher Entrepreneurial Workforce:

Reforming conflict of interest rules are critically important for civil service researchers working in government owned and operated laboratories, such as NIH. Creating new conflict of interest rules for federal researchers, similar to those employed at research universities, is vital where conflicts are managed by disinterested parties supervising the research units, with frequent and transparent reporting and approval guidelines. Current federal conflict of interest statutes do not easily accommodate the role of a federal researcher working on entrepreneurial project, which is allowed by other federal statutes. This may require federal statutory reform, as has been the experience for public research universities at the state level in the U.S.

Additionally, to ensure that federal research jobs remain attractive to younger researchers, ensuring these entrepreneurially-minded researchers have defined pathways to experiment with assignments or entrepreneurial leave is necessary. Use of Intergovernmental Personnel Act (IPA) assignments where a federal researcher might be appointed to a research university to work on is one vehicle. The Department of Energy has an entrepreneurial leave policy for researchers at Sandia Labs where researchers are allowed up-to-three years leave time to work on entrepreneurial projects, with a guarantee that the position will be open during the time period.

Federal Lab Academic and Private Sector Engagement:

Given the number of government owned-government operated federal laboratories in the Greater Washington region, it is critical to ensure that additional flexibility be granted. These might include expanded Other Transactions Authority (OTA) and expanded Enhanced Use Lease Authority (EULA) and other authorities that are currently limited to specific federal agencies, but might be given broader application across all agencies to unleash more innovation. For example, NASA Ames Research Park in California has Google as a major tenant and NASA Ames is now building new workforce housing on federally owned land. Extending this idea to all federal labs to create Public Private Partnerships (P3) with universities and the private sector is an idea worth emulating as it can reduce commuting for researchers and finance new energy efficient buildings.

We enjoyed your visit to the AURP International Conference last fall at the University of Maryland and your comments about the *Return on Investment Initiative*. We look forward to working with you and other members of the Administration and Congress on reforming our laws and regulations concerning federally sponsored research.

Thank you for the opportunity to provide further feedback.

Sincerely yours,

Daniel J. Duncan
President AURP

cc: Brian Darmody
David Baker

Transforming Ideas into Opportunities

January 9, 2019

Via email: roi@nist.gov

AUTM Comments on the NIST Return on Investment Initiative Green Paper

AUTM, a nonprofit organization dedicated to bringing research to life by supporting and enhancing global technology transfer, represents more than 3,000 technology transfer professionals, mainly in the United States and in 50+ countries worldwide. Thank you for inviting comments on NIST's Return on Investment (ROI) Initiative Green Paper. AUTM supports this effort and believes that overall the recommendations will substantially improve the current technology transfer system. AUTM is in alignment with the higher education associations as evidenced in the letter dated Jan. 9, 2019, but wanted to separately provide more detailed comments on some of the Green Paper sections. Below we raise some concerns to your attention and as particular changes are considered and drafted, encourage NIST to continue seeking input as seemingly minor details could inadvertently negatively impact our finely-tuned technology transfer ecosystem. Our comments are included in the order in which the Intended Actions appear in the Green Paper. We hope they will help increase the impact of this important effort.

1) Defining the Scope of the Government Use License (Intended Action 1)

AUTM supports this recommendation. Having additional guidance to assure our licensees that this authority is limited and will not be abused would be very helpful as AUTM members and their organizations frequently hear incorrect interpretations from their private sector partners about the breadth and scope of the statutory language defining the government's right to use resulting inventions and practice them throughout the world.

One such abuse of this right is when a licensee refuses to pay agreed upon royalties to academic institutions when they sell resulting products to federal agencies without the agency's authorization to utilize the government's right to a royalty free license. As made clear in the Government Accounting Office's report "Agencies' Rights to Federally Sponsored Biomedical Inventions" (https://www.gao.gov/new.items/d03536.pdf) cited in the Green Paper:

> "*The government's right to practice an invention is limited to federal agencies* ***and their funding recipients specifically authorized to use the invention for federal purposes*** (emphasis added)."(GAO report p. 6)
>
> "*The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license.*" (GAO p.2)
>
> "*The statute does not give the federal government the far broader right to purchase, 'off the shelf' and royalty free (i.e., at a discounted price), products that happen to incorporate a federally-funded invention when they are not produced under the government's license.*" (GAO p. 7)

Thus, it is clear the government's use license can only be invoked by the agencies or those they authorize to act on their behalf. It does not provide a pretext for those licensing federally-funded inventions to avoid paying agreed upon royalties.

Recommendation 1:

Clarify in Intended Action 1 that the government's license can only be invoked by an agency or those it officially authorizes to act on its behalf and does not automatically extend to private parties licensing federally-funded inventions who sell resulting products to a federal agency.

2) Clarifying March-in Rights (Intended Action 2)

This may be the most significant Intended Action in the report. As noted by Secretary Ross, the Bayh-Dole Act has tremendously benefitted the public welfare both here and abroad. Resulting research partnerships between academic institutions and the private sector are important drivers of our economy and bring federally-funded inventions to market for the public benefit. Yet attempts to misapply the march-in provision of the Bayh-Dole Act to regulate the price of successfully commercialized products undermines the intent of the law as evidenced by the quote from Senators Bayh and Dole in the Green Paper.

AUTM strongly supports Intended Action 2 which proposes a clarification under the Bayh-Dole regulations "specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services." We also support the effort to: "Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace but not as terms (i.e. price control mechanism) for consumer use." Implementing the new regulation removes the burden from each agency to interpret the law which is why Congress designated the Department of Commerce as the lead agency. AUTM applauds this critical reinforcement of the system that has served us so well.

Recommendation 2:

AUTM strongly supports this Intended Action 2.

3) Strengthening Preference for U.S. Manufacturing (Intended Action 3)

AUTM appreciates NIST's intention to streamline the U.S. manufacturing waiver process which has been quite challenging and unnecessarily time-consuming to AUTM members and their licensees. The technology transfer process can already be complex, particularly with small or start-up businesses, and the cumbersome and confusing waiver process can easily and unintentionally eradicate a licensing deal, meaning the product is never deployed for use by the public. Making the waiver process uniform government-wide also allows agencies to trade best practices, thus making the process more efficient.

We caution, however, that careful consideration of field-specific distinctions and the often global nature of corporate structures is essential to avoid inadvertently hampering technology development and product integration processes for certain products. For example, automobiles and mobile phones incorporate many inventions from various sources into a single product, and requiring the whole product to be substantially manufactured in the United States while a minute portion of inventions are federally-funded may cause potential licensees to wholly decline development of such inventions made by academic institutions.

NIST plans to identify the pathways for expanding the U.S. manufacturing preference to non-exclusive licenses and to all contractors. As above, we have concerns that these seemingly noble efforts to support and enhance the U.S. manufacturing base may backfire and cause less technology transfer in the long run. Additionally, it is not clear what legal authority is being used to take the proposed action as Section 204 of the Bayh-Dole Act is explicitly limited to exclusive licenses. Congress apparently recognized that anyone wanting to manufacture a product in the U.S. from a non-exclusive license could simply apply for one.

Thus, the time, expense and complexity of requiring waivers for non-exclusive licenses does not appear to be justified and would be burdensome. This may interfere with Strategy 2, increasing engagement with the private sector, as companies find these processes slow and not "speed-of-business." Also, non-exclusive licenses tend to be just-in-time licenses, executed when technology development is already underway or a product close to launch. Withholding or delaying such a license may not result in a change of manufacturing location especially if the product is close to entering the marketplace. Lastly, if the non-exclusive licensing process includes publishing an intent to grant a non-exclusive license in the Federal Register, as it does when the license is exclusive, the publicity may further discourage potential licensees.

Subsequent proposed regulations for streamlining or making additional changes to the current process must be open for additional public input, be flexible enough to encourage consistent use of the outlined processes, foster dialogue with agencies on the nuances of specific circumstances, and contain a mechanism to appeal federal decisions that may not be sufficiently apprised of particular facts of the situation. Throughout this process, NIST should exercise caution to not create conditions discouraging the development of state-of-the-art advances in technology or hamper academic or governmental institution's ability to transfer technologies for the public good. We encourage NIST to seek additional public comment and input as it develops more concrete plans to implement such provisions.

Recommendation 3:

Create a uniform waiver process for federal agencies.

Recommendation 4:

As any company that wants to domestically manufacture a non-exclusively licensed federally-funded invention can apply for a license, there is no need to include a U.S. manufacturing requirement provision for non-exclusive licenses.

4) Streamline Partnership Mechanisms (Intended Action 8)

This section describes industry "concerns about consistency in licensing practices both within labs and across labs" and related problems caused by differing agency authorities and procedures. However, Intended Action 8(C) would have the government "establish consistent, transparent licensing policies and practices for federally-funded intellectual property..." Thus, the practices of academic institutions and private contractors under the Bayh-Dole Act would be swept in through this language. A better approach would be examining why industry is having problems working with specific agencies and laboratories.

A significant achievement of the Bayh-Dole Act is that it ended government micro-management of inventions made by grantees and contractors. Secretary Ross began this exercise by saying that the federal government had a lot to learn from the success of academic technology transfer. One reason for that success is that the Bayh-Dole Act cut through the red tape previously strangling the system, while allowing flexibility for contractors and their industry partners to mold license terms to match unique and varying circumstances. The law gives the government a limited oversight role. That does not include defining licensing practices beyond those listed in the statute. Even for the federal laboratories doing so could open a Pandora's Box of unintended problems.

One theme absent from the Green Paper is accountability. Some federal agencies appear to have made the process unnecessarily cumbersome and may not be fully utilizing their current authorities according to other studies of the problem. If federal agencies and their laboratories are not held accountable for their performance, effective oversight, rather than new regulations, is a better approach.

Another concern is Intended Action 8(E). The purpose of royalties ***are not*** "primarily to promote compliance by the licensee to the terms of development and achieve practical application of the technology." That's the purpose of diligence milestones that academic institutions use to monitor development of the technology. One reason why march-in rights have not been utilized is that academic institutions will terminate a license if it appears that good faith efforts toward commercialization are not being made. Royalties, on the other hand, are a cost to the licensee, not an incentive toward development. But they are important incentives for public sector institutions to share in the success of a product they helped to discover.

It is not by accident that both the Bayh-Dole Act and the Federal Technology Transfer Act include receiving royalties for academia and federal laboratories as critical parts of their formula. Generating appropriate royalties provides an incentive for public institutions to undergo the rigors and expense of technology transfer. Under both statutes, royalties fund additional research, reward public sector inventors and researchers for participation in the process while helping to pay technology transfer expenses.

As noted by Secretary Ross, federal agencies significantly trail academic institutions in generating royalties. One reason why technology transfer may be lagging in some federal laboratories is that the rewards are minimal while the costs drain their budgets. Artificially limiting royalties exacerbates this problem and undermines Goal 3 on building a more entrepreneurial workforce in the public sector.

It is important that reasonable royalty rates be charged but that can only be determined by the nature of the invention and other factors specific to each deal, not through regulation. While doubtlessly well meaning, Intended Actions 8(C) and 8(E) as currently described raise serious concerns.

> ***Recommendation 5:***
>
> ***While AUTM supports the sharing of general licensing best practices, we do not recommend implementing specific "one size fits all" approaches through regulation due to the vast diversity and complexity of license agreements.***

5) New/Expanded Partnerships Mechanisms (Intended Action 9)

While AUTM supports in principle new mechanisms that make technology transfer more effective, there should be clear, compelling reasons for such actions. We have significant concerns about the idea of expanding the use of the "Other Transaction Authority" (OTA) through the proposed "Research Transaction Authority" (RTA) under Intended Action 9. We are also concerned that a proliferation of mechanisms, rather than holding agencies accountable for how they are utilizing existing authorities, only adds to industry's confusion with how to effectively partner with federal laboratories.

It is not clear from the description in the Green Paper why adding yet another authority allows agencies to be more efficient in completing partnering agreements with industry. It appears that one reason in the delay in processing CRADAs is due to the agencies' own procedures rather than a lack of authority. Regardless, creating a new OTA type program raises serious concerns.

Because OTA's are neither contracts, cooperative agreements, nor grants, Bayh-Dole Act rights do not apply. Intended Action 9 would spread the use of this program government-wide through the RTA. The Green Paper says that "appropriate conveyance of intellectual rights consistent with Bayh-Dole" would be done through the implementing regulations. If the purpose of the new RTA authority is as described, Bayh-Dole Act rights should be guaranteed in the legislation. Leaving such fundamental rights to the vagaries of regulation, which could be reversed in future Administrations, is a very serious concern. The history of the OTA at the Department of Defense, where it originated, proves this is not an idle fear.

Here's how a December 14, 2018 article (https://www.jdsupra.com/legalnews/dod-issues-new-other-transactions-guide-74710/) describes the new OTA guidance from the Department:

> *While both the new and old guides confirm that the Bayh-Dole Act, 35 U.S.C. §201-204 for patents and 10 U.S.C. §2320-21 for technical data, do not apply to OTs, the new guide encourages more latitude in negotiating appropriate IP clauses. Specifically, the prior guide stated:*
>
> > *The Agreements Officer should seek to obtain intellectual property rights consistent with the Bayh-Dole Act (35 U.S.C. §201-204) for patents and 10 U.S.C. §2320-21 for technical data and computer software. Negotiation of rights of a different scope is permitted when necessary to accomplish program objectives and foster Government interests, and to balance the interests of the awardee.*
>
> *The new OT Guide instructs that "these statutes do not apply to OTs and* **negotiation of rights of a different scope is permissible and encouraged***" (emphasis in original). Where the language of the prior guide appeared to reflect a grudging admission that deviation from standard IP clauses was permitted, the new guide provides, in bold type, that different terms are encouraged.*

An express purpose of Congress in passing the successful Bayh-Dole Act was to create a uniform patent policy across all government agencies. The existing OTA undermines that goal, and a new RTA could further harm that objective. As Secretary Ross stated, the success of academic technology transfer under the Bayh-Dole Act is the centerpiece of our technology transfer system. It has yielded significant returns on investment for the American taxpayer. It is hard to see how denying Bayh-Dole Act rights to academic institutions and small businesses so inventions can be given to prime contractors serves the public interest.

The need for creating any new authority should be seriously weighed and documented. If there is ample reason for doing so, Bayh-Dole Act rights should be protected in the statute to secure the greatest return on investment from federal research and development (R&D).

Recommendation 6:

Do not create any new partnering mechanisms built upon the OTA model that denies Bayh-Dole Act rights to grantees and contractors.

6) Establish a modern platform for reporting data on intellectual property resulting from federal R&D (Intended Action 13)

Information about the fruits of research expenditures, such as how often research succeeds, and the results produced, change what we as a society are willing to fund, and the entities willing to fund it. We strongly support Intended Action 13, on modernizing a platform for reporting data on intellectual property resulting from federal R&D. We caution against an overly narrow or literal interpretation of recommendation 10.2 in the 2016 National Academies of Sciences report cited in the Green Paper at footnote 271:

> *10.2 The Department of Commerce, in consultation with the proposed Research Policy Board, should develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act.*

Applying a "do not exceed the statute" approach to reporting under the Stevenson-Wydler Act could interfere with Goal 5, and thus the initiative on enhancing the national return on research investment overall.

We suggest that some of the requirements currently in the statute may be less helpful, for example, on reporting the skew in the license income:

> *the total earned royalty income including such statistical information as the total earned royalty income, of the top 1 percent, 5 percent, and 20 percent of the licenses, the range of royalty income, and the median, except where disclosure of such information would reveal the amount of royalty income associated with an individual license or licensee;*

It may be more useful to report the fraction of licenses to small business and start-up businesses, or the fraction to domestic licensees.

> ***Recommendation 7A:***
>
> ***Engage with a working group of compliance and reporting stakeholder users of such a platform, including AUTM members, to develop user interface and performance specifications.***
>
> ***Recommendation 7B:***
>
> ***Create a modernized, secure, inter-organizational system for reporting to all federal agencies on intellectual property resulting from federal R&D, leveraging off of iEdison if possible.***
>
> ***Recommendation 7C:***
>
> ***Manage the project to interim deliverables.***

Recommendation 7D:

Engage with a working group of Goal 5 users, namely the stakeholders who want to use the information to better understand global science and technology trends and benchmarks, and take their requests into account.

7) Establish a federated data portal that is easy for the public to access, use and analyze (Intended Action 14)

We strongly support Intended Action 14, on establishing a curated data portal on intellectual property and federal R&D programs for public benefit, mindful of the need to build in an approach to documenting and moderating access to such a portal so it is consistent with an overall goal of supporting U.S. manufacturing.

Use of such a portal may provide a valuable opportunity to contribute to Goal 2. Simple web analytics on the number of sessions, users, page views, pages/session, average session duration, bounce rate, and others may provide insight into the interest in and demand for technologies. If users are required to register, it will also further contribute to Goal 2, leading to an increase in corporate engagement, as it would potentially enable more targeted marketing.

AUTM has developed a robust technology transfer portal called the "AUTM Innovation Marketplace" or "AIM" (https://aim.autm.net/) which currently lists almost 20,000 technologies available for licensing from over 170 institutions. AIM provides many of the features listed above, along with the ability to sign up for customized alerts based on keywords.

Recommendation 8A:

Engage with a working group of federal laboratory technology transfer practitioners and their potential customers to i) develop content and operational specifications for the portal and ii) monitor results and refine the content and specifications as needed.

Recommendation 8B:

Develop a prototype portal, or join AUTM's interactive AIM portal.

Recommendation 8C:

Improve the portal and marketing processes based on user experience, customer feedback and data.

8) Establish metrics to better capture, assess, and improve federal R&D outcomes, impacts, and operational process (Intended Action 15)

AUTM cautions against *de novo* reframing and instead supports continuous improvement of current approaches to understanding short term, long term, local, diffuse, societal, and economic impacts of federal research. These impacts are intertwined and not readily separable.

AUTM commends the recognition in the Green Paper (page 110) that a number often criticized as leading to an overemphasis on economic returns -earned royalties- is the same number which is the basis of a jobs estimate - a societal return.

> *"For example, government metrics that include a monetary return on investment in the form of royalties for patents licensed are used to understand the more valuable metrics for government performance in job creation, economic competitiveness, and national security capabilities."*

Key science and engineering indicators and macroeconomic concepts, such as gross domestic product (GDP), have been developed and refined over decades and generations, technology transfer indicators will similarly be developed over decades and generations. We appreciate the mention of the data in figure 3 of the AUTM/BIO report on page 108 which would not have been possible without two decades of standardized academic technology transfer data. The data provide quantitative support for the importance of new products to prosperity. Such a result would not be possible without standard and routine data collection with well-established definitions for the data collected, including data on royalty payments.

The authors of the AUTM/BIO report were unable to generate an analogous figure for the federal laboratories because of a lack of consistently defined data elements over time. Just as overly or prematurely standardized approaches risk missing key insights, overly unique approaches do not lead to actionable insights and are not conducive to continuous improvement.

AUTM both welcomes federal laboratories to submit to our Annual Licensing Activity Survey as well as the opportunity to help develop additional appropriate and meaningful measures of success. Management consultant Peter Drucker once said "If you can't measure it, you can't improve it."

Technology transfer at its core is about sharing risks and rewards among transferors and transferees. Sharing, or trading, occurs more easily with experience, and with the trust in the process built by such experience. Neither insurance, nor investments in early technology would exist if we did not understand, and have documented experiences with patterns of success and failure.

Recommendation 9:

Rename Intended Action 15 to "Continuously improve our approaches to and metrics for understanding and improving federal R&D outcomes, impacts, and operational processes."

Recommendation 10A:

Form and support a working group, which includes a cross section of federal laboratory technology transfer practitioners from the agencies with federal laboratories; representative laboratory types: GOCO's, GOGO's and FFRDC's; and expert advisors, such as economists, historians, and AUTM members who have grappled with analogous issues.

Recommendation 10B:

Task the group with defining data elements to count, measure, observe and document.

Recommendation 10C:

Implement their recommendations, leveraging off of AUTM Survey infrastructure if it is possible and efficient to do so, and improve measures based on experience and feedback from the working group.

Additional Recommendation

In addition to the 15 Intended Actions identified by NIST, AUTM recommends another crucial safeguard for our technology transfer system. Congress enacted the Bayh-Dole Act to create a uniform patent policy across all agencies. In doing so, it recognized that this goal would unravel over time without oversight. That is why the law designated this critical role to the Secretary of Commerce. For too many years, this function has been neglected and some agencies began denying Bayh-Dole rights inappropriately for grants, cooperative agreements, and contracts by misapplying the exceptional circumstances provision of the law or promoting alternative mechanisms like the previously discussed OTA. AUTM applauds the renewed attention that the Department is now giving to its statutory duties. Effective oversight is critical to the continued success of the Bayh-Dole Act which was appropriately lauded by Secretary Ross when launching the ROI Initiative.

Recommendation 11:

AUTM sees it as critically important for maximizing the return on investment from extramural research & development that the Department of Commerce effectively oversees the Bayh-Dole Act to ensure that all agencies are in compliance.

Thank you for providing this opportunity to comment on the Green Paper. AUTM looks forward to working with NIST in creating the greatest possible return on investment from the taxpayer's investment in federally-funded R&D. Please do not hesitate to contact us if there are any questions regarding the above comments.

Stephen J Susalka

Stephen J. Susalka, PhD, RTTP, CLP
AUTM CEO

About AUTM

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of more than 3,000 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

EAGLE FORUM
EDUCATION & LEGAL DEFENSE FUND

Benefiting from Federal Research Funding

Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society

Proceedings
of
Capitol Hill Briefing

Cannon House Office Building
Washington, D.C.
October 18, 2018

Hosted by Eagle Forum Education & Legal Defense Fund

> "One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property."
>
> *Congressional Research Service*

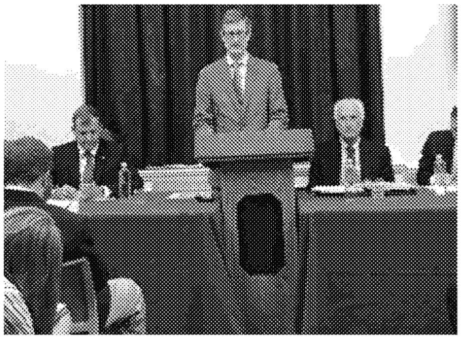
Benefiting from Federal Research Funding

Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society

Eagle Forum Education & Legal Defense Fund hosted an October 18, 2018, briefing, where a packed room of congressional staff, industry representatives, and policy experts heard experts discuss the transfer of discoveries from federal research funding and the benefits to society. Panelists explained how the Bayh-Dole Act fosters commercialization of inventions from federal funding of basic research by letting universities own the patents to their inventions.

Eagle Forum Education President Ed Martin welcomed attendees, Patent Policy Advisor **James Edwards** moderated the panel discussion, and panelists **Joseph Allen**, former Senate Judiciary Committee aide to Sen. Bayh and Reagan administration Commerce Department official; **Stephen Susalka**, chief executive officer of **AUTM**; **Hans Sauer**, deputy general counsel and vice president of the **Biotechnology Innovation Organization**; and **Stephen Ezell**, vice president for global innovation policy at the **Information Technology & Innovation Foundation**, each spoke. Summaries of panelists' remarks follow in the order of speaking.

Takeaways included that patents and exclusive licensing deals justify private investors' backing the long, expensive, uncertain path of applied research and development. Secure, exclusive patent rights under Bayh-Dole translate into $5-$10 in private investment to commercialize an invention for every dollar of federal basic research funding. Most of the patents get licensed to small businesses and startups for commercializing. The success of university tech transfer contrasts with that of federal labs, far outpacing federal agency performance.



James Edwards, Moderator

Patent Policy Advisor, Eagle Forum Education & Legal Defense Fund

Our briefing today centers on this question: How can we get society the greatest benefit from the discoveries made from the hundreds of billions of federal research dollars that go to universities and federal facilities?

That's what the National Institute of Standards and Technology seeks to answer through its Return on Investment Initiative. This past spring, NIST put out a Request for Information and has convened listening sessions. Eagle Forum Education and most of the groups on our panel responded to NIST's RFI.

First, a little context. Federal funding supports basic research — discovering fundamental scientific knowledge. To get practical use from that new knowledge, there's a whole different, lengthy, expensive process. It involves applied research, development and commercialization. Private investment supports this stage. To move a discovery from basic research to commercialization, the new technology must be handed off to a company or entrepreneur willing to attempt its commercialization. That's technology transfer.

To restate the basic question: How can society get the most benefit from federally funded research?

Fortunately, this question's been asked and answered over the past 40 years. The bipartisan Bayh-Dole Act intentionally employs secure, exclusive intellectual property rights as the vehicle for commercializing federally funded discoveries. Bayh-Dole is a game-changer. Before Bayh-Dole, the government owned 28,000 patents with fewer than 5% commercialized. Bayh-Dole opened the floodgates.

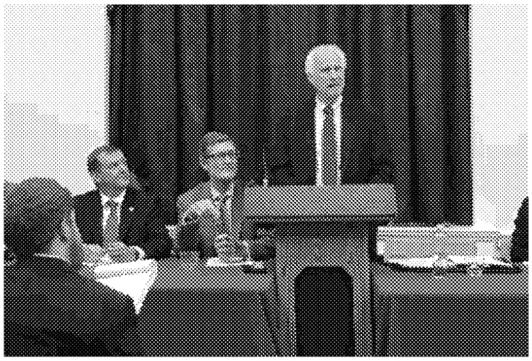
As the Congressional Research Service put it, "One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property." Bayh-Dole teaches that secure patent rights are the lynchpin to society getting the greatest benefit from federal research dollars.

And NIST Director Walter Copan is right to examine how federal research facilities could improve their tech transfer record. Commerce Secretary Wilbur Ross points out how federal agencies trail universities in this area. Secretary Ross says "federally funded university research is about five times more likely to result in a licensed patent technology and about seven times more likely to result in an active patent license" than federal agencies.

The solution is straightforward. As Eagle Forum Education put it in our RFI comments: "The best, most cost-effective and efficient means of improving the return on investment of federal labs' discoveries is to adopt the attributes of the highly successful U.S. private-sector patent licensing and commercialization as well as the Bayh-Dole regime."

Our briefing explores technology transfer and secure property rights as the keys for society to benefit from our taxpayer dollars at work in research. Our panel will discuss the Bayh-Dole Act and its record of commercialization success, along with threats to its continued success. We'll talk about improving federal tech transfer. We'll also see how patents and IP turn basic research into new medicines, new advanced materials, new energy and agriculture, and new manufacturing and other technologies. We have distinguished panelists for this timely discussion.

> *"The Bayh-Dole Act's running like a finely tuned machine and doesn't need any legislative tinkering. However, it must be maintained. The Department of Commerce is charged with overseeing the law so that it's properly implemented. Unfortunately, the Department's been missing in action. . . .*
>
> *"Commercialization remains a neglected step child in many agencies. Government technology managers are often hamstrung from effectively making deals by bureaucratic procedures and second guessing from agency lawyers. Many lab directors and middle managers see tech transfer as an unfunded mandate, taking time and resources away from their mission. What's needed is a signal that business as usual is over."*
>
> *Joseph P. Allen, comments filed with the National Institute of Standards and Technology to its Request for Information Regarding Federal Technology Transfer Authorities and Processes*



Joseph P. Allen

President, Joseph Allen & Associates; former Senate Judiciary aide

It's always fun talking about the importance of federally funded R&D because something new is always coming out. Just a couple of days ago, the headline article in the *Wall Street Journal*'s Review section was "The Great American Growth Machine" by former Federal Reserve Chairman Alan Greenspan and Adrian Wooldridge with *The Economist.* Here's what they said:

"Today, the United States has the most powerful economy in the world: with less than 5% of the world's population, it still accounts for almost a quarter of global GDP. America has the world's highest standard of living apart from a handful of countries with small populations ... It also dominates the industries that are inventing the future — intelligent robots, driverless cars, life-extending drugs. The fact that 15 of the world's top 20 universities are based in the U.S. ... suggests that it is well-placed to dominate the ideas economy."

That last sentence would not have been written 40 years ago because at that time the government took inventions away from our universities and made them freely available to any and all. The result was that few were developed here. The Bayh-Dole Act stopped the giveaway of inventions made with billions of dollars of taxpayer-supported R&D. It injected the incentives of patent ownership into the system, decentralized technology management from Washington to the creators of inventions made with government support, gave preferences to licensing small companies and those who would manufacture resulting products here while allowing the government to use discoveries it had helped fund. This change in policy, combined with a strengthening of our patent laws, ignited one of the greatest industrial Renaissances in history.

It's hard to remember now, but in the 1970s it looked like America had permanently lost its lead in critical fields of technology. Japan and Germany had taken away our lead in fields like electronics, automobiles, and steel, and it looked like just a question of time before others were lost as well. But that didn't happen because Bayh-Dole helped unleash the American entrepreneurial spirit.

President Lincoln said the patent system "adds the fuel of interest to the fire of genius." Lincoln was our only president who owned a patent, so he knew what he was talking about.

The government funds research for two reasons: to meet its mission needs and to further the frontiers of science. Neither is geared towards developing new products, so resulting discoveries are very early stage, more like ideas than anything that can be sold in stores. Thus, partnerships with industry are critical if the public is to receive the full benefits from $150 billion spent every year in government-supported research. These companies typically invest many times what the government spent in the initial research, with no guarantee of success. They simply can't take that risk without strong intellectual property rights to protect the risk and expense of commercialization.

The numbers tell the story. Before the Bayh-Dole Act, the government accumulated 28,000 inventions and less than 5% were licensed. Not a single new drug was developed when the government took inventions away from the creating institution. Congress saw that keeping these discoveries on the shelf was a waste we could no longer afford.

Bayh-Dole triggered an explosion of creativity. The U.S. biotechnology industry is founded on university-industry research partnerships founded on the law. More than two new companies and two new products are developed every day from university inventions. Academic patent licensing contributed $1.13 trillion to our economy while supporting more than 4 million new jobs over a 15-year period. No other country comes close to matching these numbers. Indeed, Bayh-Dole has become the gold standard of technology management and is widely copied around the world.

Yet for all of its accomplishments, a small band of critics is determined to roll back the clock. They urge a return to government micromanagement while disparaging our patent system, which is in disrepair. We can't afford to go backwards for many reasons.

While we rightly tout the economic impact of Bayh-Dole, there's another story we shouldn't forget. Several years ago, we celebrated the 30th anniversary of Bayh-Dole. There were many impressive speakers, including Sen. Birch Bayh, dignitaries from the Patent and Trademark Office, and industry. But of all that was said that day, I can only remember one thing. The very last speaker on the program was a cancer survivor, Betsy de Parry. As she approached the microphone, she suddenly turned around, walked up to Sen. Bayh, and wrapped him in her arms, saying, "If not for your law, I would not be alive today." If there was a dry eye in the house, it wasn't mine.

Stories like that are our real success. We owe it to people like Betsy to make sure our laws incentivize commercialization so the benefits of federally funded research get out of the labs and into the marketplace where they help make the world a better place.

Stephen Susalka

Chief Executive Officer, AUTM

AUTM is a nonprofit association focused on empowering, promoting, and connecting our 3,100-plus technology transfer professionals who make the world a better place through the commercialization of academic and other nonprofit innovations.

While you might not be familiar with technology transfer, you've undoubtedly used many of the products and services originating from universities, hospitals, and research labs. Among the tens of thousands are:

- Allegra for severe allergy sufferers, thanks to Georgetown University
- Robotic exoskeletons to help those with paralysis from the University of California, Berkeley
- FluMist for kids who hate shots, out of the University of Michigan and St. Louis University
- The nicotine patch for people who want to quit smoking, which UCLA created
- Rotavirus vaccine came from Cincinnati's Children's Hospital
- Even Honeycrisp apples! They're from the University of Minnesota.

All these inventions were originally developed at universities and commercialized because of tech transfer. But we didn't always have such a robust innovation ecosystem, and it quickly accelerated with the passage of the Bayh-Dole Act in 1980.

It is the Bayh-Dole Act that has played a pivotal role in the unleashing of American innovation and is now the gold standard that countries are adopting around the world. In order to maximize the impact of our predominantly taxpayer research, we must keep investment strong, strengthen our patent rights, and protect the core of what turned us into the most innovative economy globally: the Bayh-Dole Act.

So, what is tech transfer?

Tech transfer involves moving inventions and discoveries made in university labs to those who can develop them for commercial use. Professionals in the field help make that happen. The process involves evaluation, protection, and commercialization.

The critical accelerant to this process is research funding. There's a linear relationship of research funding to inventions. On average, $2.7 million in research funding is behind each invention. Researchers discover something in the lab that potentially could be translated into practical application. That's where technology transfer professionals come in.

First, evaluation. This is where professionals look at two major aspects: if the invention is commercializable and protectable. Commercializable means the research finding could be turned into a product or process that's commercially useful.

Second, protection. Protectable generally means it's patentable. Is the discovery new, practically useful, and not obvious? Protecting the institution's ownership rights in an invention is critical. At this point, the intellectual property is really all the university has. Strong, consistent patent rights are essential; otherwise the inventions will die on the vine.

Third, commercialization. Universities don't sell inventions. Instead, they license those inventions to companies to further develop and sell the resulting products. Licenses come in two flavors – licenses to existing companies and licenses to new start-up companies. Royalty revenue goes back to the university and individual inventors to fund the next generation of inventions.

By the numbers

Since 1991, AUTM has been collecting licensing survey data in the U.S. The data show that university tech transfer, which Bayh-Dole enables, has been a tremendous success.

Going around the lifecycle, in 2017, a record $68.2 billion in research expenditures is reported – a new high and up 2 percent from the previous year. That research funding led to almost 25,000 invention disclosures. However, that was the first decline (albeit very modest) we've seen in 27 years of data. This could be the proverbial canary in the coal mine regarding the negative impact of the weakening of the patent process – the fear is that ideas will not be disclosed, and potential innovations will never make it to market.

While we hit a record of patents issuing — 7,459 — keep in mind they take 3-7 years on average, so they've been in the pipeline for a long time. However, new patent applications, 15,335 in 2017, have declined by almost 10 percent in the last five years – a troubling trend, again likely driven by the weakening of the patent system.

We saw 7,849 licenses and options reported. Each of those could be for the next life-changing invention like the ones we have seen; and 755 new products were created in 2017 alone. Another bright spot was the growth in start-up companies, which grew to a record 1,080 in 2017 – a 5.5 percent increase. Importantly, more than 72 percent of those start-ups are headquartered in the home state of the institution, which leads to local and regional economic development.

Taken together, these results show that the research engine continues to be strong, but the uncertainty in the value of patents more recently has begun to affect the number of inventions and patent applications – the raw materials that blossom into products, companies, and jobs.

A separate report detailed the economic impact of tech transfer activity. A joint AUTM-BIO report found, over a 20-year period, up to $591 billion added to the GDP and up to 4.3 million jobs supported.

AUTM and BIO are anticipating the release of a joint follow-up report in 2019.

About AUTM

AUTM is the nonprofit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of more than 3,100 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

AUTM's members work closely with commercial partners to transform ideas into opportunities, resulting in the creation each year of thousands of products, services and start-ups, and millions of dollars in economic development. First and foremost, their work means improved lives, every day, everywhere.

AUTM advocates and supports the full spectrum of its members' work – from corporate engagement to intellectual property protection — empowering dynamic, forward-leading professional practices and advancing current and future generations of leaders in the field of technology transfer.

> *"Universities seem to be doing far better than the federal labs and can teach us a thing or two. . . . Recent studies have shown that federally funded university research is about five times more likely to result in a licensed patent technology and about seven times more likely to result in an active patent license. Universities received $1.78 billion in licensing revenue from their innovations in 2014. In comparison, the total amount of royalties received from licensing government inventions was only $194 million in 2014, the latest year for which data are available. In that year, universities received $66½ billion for R&D while federal labs received $42 billion.*
>
> *"Now if you do the math, universities received just over 50% of the R&D funding, but licensed nearly 10 times the value of technology. One would imagine that the gap has widened even further, as university activity has exploded, generating $2.96 billion in licensing income from their inventions in 2016.*
>
> *"Now obviously, R&D in a given year is not what has resulted in royalty income in that year because of leads and lags. But the pattern has persisted long enough, and the math is so lopsided that it seems to me that there is a message in it."*
>
> *Secretary of Commerce Wilbur Ross*

Hans Sauer

Deputy General Counsel and Vice President, Biotechnology Innovation Organization

The Biotechnology Innovation Organization is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotech products.

BIO's membership includes many small biotech companies. Small companies hold 70% of the drug development pipeline. The United States originates more new drugs than the rest of the world combined: 57% of new drugs come from this country.

The U.S. government generously funds biomedical R&D. The National Institutes of Health budget is over $30 billion. But the biggest contributor is industry; industry spends over $100 billion annually on R&D.

As you've heard, the roles of industry and publicly funded research institutions are different, and that's true in the biomedical field as well. So the relative monetary contributions, public and private, pay for different, but related things. Public funds are for basic research; industry funds are for applied research and development.

Not all publicly funded biomedical research ends up being commercially relevant, but a large proportion does. Estimates are that around 20-30% of NIH grants result in research that later becomes relevant to new drugs. This is what people mean when they say that the federal government funded the creation of new drugs.

Federal funding generally doesn't pay for the cost of developing a new drug, but it paid for much of the scientific foundation. Once the cause of disease is understood, that provides opportunities then to devise new treatments or better diagnostics, whose development must also be funded. You can think of it as a kind of infrastructure investment. "When the railroad comes," businesses start popping up, commerce grows around it. We have many historic examples of this — early federal post and military roads and canals fueled expansion to the Ohio River. Railroads drove expansion further west. Electrification, the Interstate Highway

System, all these are examples of public investments that, amongst other things, provided the foundation and opportunities for private enterprise, and raised overall prosperity.

Even today, economists fix the return on investment for federal transportation infrastructure grants at around 2, meaning every federal dollar spent on improving roads or rail results in a $2 increase in the state's economic output. I want to propose to you that federal funding of basic biomedical research is likewise a good form of investment, a foundation that mobilizes and pulls along large amounts of private investment.

We know that, on average, for every new drug, companies and their investors spend out-of-pocket private funds approaching $1.3 billion per drug, over an almost 10-year R&D period. What's more, almost 9 out of 10 new experimental drugs that enter clinical development fail at some point and are never approved for human use.

When you put this together, this means that, through the Bayh-Dole Act, the public investment in biomedical R&D becomes very highly leveraged – every public research dollar recruits 5-10 or more private dollars for subsequent, applied R&D. This is money the government would otherwise have to spend. And remember the 90% failure rate in drug development.

The Bayh-Dole Act provides the incentive for the private sector to step up and assume that risk of failure, which otherwise would have to be borne by the government. We normally don't want large amounts of taxpayer dollars to go to projects that have 90% failure rates, so recruiting the private sector through the Bayh-Dole Act seems like pretty smart policy that saves the taxpayer money and risk.

- *Promote strong IP rights for private-sector commercialization.*
- *Establish high-level technology transfer oversight and accountability.*
- *Align incentives for improving agency technology transfer.*
- *Enable federal inventor and tech transfer officer entrepreneurial opportunities.*

Andrew Schlafly, recommendations filed on behalf of Eagle Forum Education with the National Institute of Standards and Technology to its Request for Information Regarding Federal Technology Transfer Authorities and Processes

Stephen Ezell

Vice President for Global Innovation Policy, Information Technology & Innovation Foundation

As my fellow panelists have elegantly articulated, the Bayh-Dole Act truly has been an unparalleled success. As *The Economist* has written, Bayh-Dole was "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century .... It unlocked all the inventions and discoveries that had been made in American laboratories throughout the United States with the help of taxpayers' money" and helped bring them to market.

Enterprises need to be able to license intellectual property or technology with the knowledge those IP rights will be secure, giving them confidence to engage in the difficult, risky, uncertain, and expensive process of investing in new-to-the-world products, especially in the life-sciences, where bringing a new prescription medicine to market can take 12-14 years and cost as much as $2.6 billion. Moreover, the life-sciences industry is the world's most R&D-intensive, investing 21% of its sales in R&D, and — like all innovative industries — it fundamentally depends on the profits earned from one generation of biomedical innovation to finance investment in the next.

Yet, despite Bayh-Dole's well-documented success, some have advocated for policies that would significantly compromise it. In particular, I'm referring to calls to employ Bayh-Dole "march-in rights" to control drug prices. "March-in rights" refer to a provision within the act permitting the federal government — in extremely specified and limited circumstances — to "march-in" and require holders of patents derived from publicly funded R&D to issue a license for the intellectual property to others. The Bayh-Dole Act proscribes only three principle instances in which the government would be permitted to exercise march-in rights:

- If the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;
- If action is necessary to alleviate health or safety needs which are not reasonably satisfied by the patent holder or its licensees;
- If action is necessary, in exigent cases, because the patented product can't be manufactured substantially in the United States.

You'll note that none of these cases addresses the price of the patented innovation (whether it be a medicine or another product). That's because, as Senator Birch Bayh himself has explained, Bayh-Dole's march-in rights were never intended to control or ensure "reasonable prices" (in fact, the Bayh-Dole Act contains no definition thereof).

Rather, Bayh-Dole's march-in provisions were designed as a fail-safe for limited instances in which a licensee might not be making a good-faith effort to bring an invention to market or when national emergencies require that more product is needed than a licensee is capable of producing. And that's part of the reason why — even though at least six petitions have been filed requesting that the National Institutes of Health "march in" with respect to a particular pharmaceutical drug — the NIH has denied all six petitions, with the agency noting that the drugs in question were in virtually all cases adequately supplied and NIH explaining that "the extraordinary remedy of march-in is not an appropriate means of controlling prices." Moreover, it's part of the reason why march-in rights have never been exercised during the 38-year history of the Bayh-Dole Act.

Put simply, if the government ever had the ability to go back, after a business had commercialized a product, and mandate the business license the product to someone else, it would destroy Bayh-Dole and any private business incentive to commercialize a product supported by federally funded research.

Some assert that taxpayers are "paying twice" when taxpayer dollars supports basic biomedical scientific research, which may lead to scientific discoveries ultimately leading to therapeutic disease targets or to insight toward chemical or biologic compounds that are commercialized into safe and effective drugs. But this misses that basic scientific research accounts for but a small fraction of the cost of bringing a prescription medicine to market. In fact, one study finds that companies invest $100 in development for every $1 the government invests in research leading to an invention or discovery. And it's why the Tufts Center for the Study of Drug Development finds that, among 35 drugs and drug classes, private-sector research was responsible for central advances in basic science for 7, in applied science for 34, and in the development of drugs yielding improved clinical performance or manufacturing processes for 28. In other words, public and private investment toward biomedical innovation are complements. We need both.

And that's why other proposals — such as "delinkage," which seeks to separate the linkage between patents for pharmaceutical products, and the profits earned from them, to finance investment in future generations of biomedical innovation or the notion that NIH might fully take over drug development — are also wanting. First, they imply that the government would make better allocation decisions than industry, despite the fact that there's little evidence for this. As the report "Wealth, Health and International Trade in the 21st Century" observes, "It's questionable that public sector actors would be more efficient in allocating resources to research scientists and others working in pharmaceutical R&D than private sector decision-makers for whom efficiency is vital."

A second problem with these proposed alternatives is they have a virtually nil track record of delivering breakthrough prescription medicines to market. In fact, not a single new drug was created from federally funded inventions under the previous to Bayh-Dole policies; whereas a system predicated on genuine innovation supported by the protection of intellectual property rights has resulted in decades of breakthrough biomedical innovation and over 7,000 new-to-the-world drugs under development today.

In conclusion, I'd like to share an observation made by Jack Scannell, a Senior Fellow at Oxford University's Center for the Advancement of Sustainable Medical Innovation (CASMI). As he wrote in a 2015 paper, "I would guess that one can buy today, at rock-bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere in the world, at any price in 1995." He continued, "Nearly all that generic medicine chest was created by firms who invested in R&D to win future profits; short-term financial gain building a long-term common good." We need to be able say, in the year 2040, that patients have access, at rock-bottom generic prices, to a set of pharmaceutical and biological drugs — including breakthrough treatments today such as Avastin or Keytruda for various forms of cancer — that have greater medical utility than the entire set available to anyone, anywhere in the world, at any price in the year 2020.

But that will only happen if we preserve a system of robust intellectual property rights, including the Bayh-Dole Act, that incentivizes innovation and allows enterprise to earn sufficient revenues to reinvest in R&D in a virtuous cycle toward future generations of biomedical innovation.

NEW BOOK!
PHYLLIS SCHLAFLY
EDITED BY ED MARTIN

PHYLLIS SCHLAFLY SPEAKS
VOLUME 4
PATENTS & INVENTION

This volume represents another chance to appreciate the full extent of Phyllis Schlafly's multi-faceted legacy! She engaged on a broad range of issues including invention, patents, and intellectual property.

"Foreign countries are free to copy our system. Instead, they want to copy our inventions."
Phyllis Schlafly

Americans owe Phyllis Schlafly a debt for "a public life well-lived" in the context of her important work upholding the core values and traditions of this country.

Phyllis Schlafly was a national political leader whose career began in 1946 when she managed a congressional campaign and culminated in 2016 when she endorsed Donald Trump for President. She is widely considered the founder of the American conservative movement.

Ed Martin is President of Phyllis Schlafly Eagles and was selected by Phyllis Schlafly to succeed her. He has served as a member of the Republican National Committee and chairman of the Missouri Republican Party.

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January 7, 2019

RE: **RFI Response: ROI Green Paper**

Dear NIST Adminstrator:

Thank you for the opportunity to provide comments on the December 2018 Draft Green Paper, "Return on Investment Initiative for Unleashing American Innovation" (NIST Special Publication 1234).

I currently serve as the Director of the Center for Military Medicine Research (CMMR) at the University of Pittsburgh. CMMR carries out research in regenerative medicine, reconstructive surgery, tissue engineering, and acute lung injury in support of the Department of Defense and Veterans Administration missions. At CMMR, we have established a successful network of partnerships and collaborations among scientists, clinicians, industry, the DoD and VA. Before coming to Pitt, I was on active duty in the U.S. Army for 30 years with extended assignments at the Walter Reed National Military Medical Center, Bethesda, MD and at the US Army Medical Research and Materiel Command (USAMRMC), Fort Detrick, MD where I served as the Deputy Director of the Telemedicine and Advanced Technology Research Center (TATRC) from 2006-2012. There I managed large medical research programs and developed novel research programs and technologies in medical informatics and telemedicine. I am acutely interested in issues raised in the Green Paper, since I understand how essential the successful translation of medical technology from lab to market is if research is to impact mission. I offer the following two comments, which I believe can make implementation of the Green Paper's recommendations more effective.

[1] Regarding the intended action for technology maturation funding (Strategy 2.D), I echo the previous respondents concerns about ensuring that adequate funding is available to support the transition of the basic science and technology research efforts through advanced development processes that lead to commercial products and solutions. Although the Green Paper provides examples of several agency-specific technology maturation programs (p 65-66), more than modifications to the SBIR/STTR program is required (Intended Action 10). OSTP working with OMB should undertake a more in-depth review of funding mechanisms on an agency-by-agency basis to assess where there are programmatic gaps and make recommendations how resources allocations can be optimized to facilitate commercialization of promising technologies and solutions.

[2] Many of the recommendations in the R&D ROI Green Paper have strong resonance with the work done through the National Network for Manufacturing Innovation (aka, Manufacturing USA). However, success requires more than just policy changes or increased levels of training; active

efforts at coordination are necessary. OSTP and NIST should seek to leverage existing networks built through prior investments in the 17 Manufacturing USA Institutes the successful model promulgated under the Manufacturing USA program. These Institutes are currently sponsored by either DoD or DOE, so other agencies should investigate whether there are appropriate opportunities to bring their programs and performers into those existing Manufacturing USA networks. Where that is not practical, other agencies should look to the Manufacturing USA Institute model for establishing a limited number of high-priority technology transfer networks.

Sincerely,

Ronald Poropatich, MD, MS
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January 9, 2019

Technology Partnerships Office
National Institute of Standards and Technology
100 Bureau Drive MS 2201
Gaithersburg, MD 20899

RE: NIST Green Paper Discussion Draft

To Whom It May Concern:

Eagle Forum Education and Legal Defense Fund ("Eagle Forum ELDF"), a nonprofit organization founded by Phyllis Schlafly[1] in 1981, is pleased to provide comments on the draft Green Paper of the Return on Investment Initiative for Unleashing American Innovation.[2] Eagle Forum ELDF appreciated the opportunity to give input through the Request for Information (RFI) last summer and now to respond to the effort to digest and incorporate the feedback from that RFI.[3]

We commend the National Institute of Standards and Technology (NIST) on this Green Paper. This includes its assessment of the issues that have kept federal agency and research laboratory technology transfer from performing as well as it should, the five main strategies for improving federal agency and laboratory performance in transferring technology for practical use, and most of the intended actions for implementing these strategies. Concerns early in this initiative surrounded whether the initiative might end up too modest, too extensive, or miss the target (e.g., misplace focus on amending the well-functioning Bayh-Dole Act instead of making adjustments to the Stevenson-Wydler Act and the Federal Technology Transfer Act, which more directly address federal government technology transfer). However, the Green Paper's proposals, in general, place the focus where it belongs, offer reasonable and measured intended actions, and largely avoid missteps. Yet, we do have a major concern with a recommendation we fear goes astray.

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[1] Phyllis Schlafly was an outspoken advocate of the rights of inventors, emphasizing the importance of these traditional rights to our national prosperity and security. She wrote often about this topic. A compilation of her writings on this topic is Phyllis Schlafly Speaks, ***Patents & Invention***. Skellig America, 2018 (Ed Martin, Editor).

[2] National Institute of Standards and Technology Special Publication 1234 (December 2018).

[3] 83 FR 19052. Request for Information Regarding Federal Technology Transfer Authorities and Processes, May 1, 2018.

Importantly, the document affirms “the critical importance of private rights in innovation as an enduring, foundational principle” and reflects appropriate respect for what we called the “first principles” that underlie every attempt to turn an invention into something that is commercially viable, whether through tech transfer or otherwise. Effective technology transfer, notably as seen in the long, successful track record of the Bayh-Dole Act, relies on exclusive, enforceable, private property rights.

Further, the Green Paper recognizes the “intimate connection between a competitive economy and national security,” which Eagle Forum ELDF has long emphasized, sometimes as a voice in the wilderness. Thus, we applaud the overarching goals of this initiative. This includes transferring IP-based technology derived from federal research funding to U.S. entities in the private sector willing to pursue those inventions’ commercialization so as to gain for society the practical benefits of such discoveries, and thereby contribute to the flourishing of the U.S. industrial base and jobs and our economy. This promotes the welfare and innovation leadership of the United States, such that Americans might continue to have national security, liberty, and independence.

Eagle Forum ELDF commends NIST for reflecting most of our recommendations from the RFI among many of the Green Paper’s specific proposals. They would promote strong IP rights for private-sector commercialization, increase accountability for federal technology transfer, align incentives for improving agency tech transfer, and enable federal inventors and tech transfer officers greater entrepreneurial opportunities. We now offer comments on several specifics in the Green Paper. These include patent reforms, government use license, march-in rights, and preference for U.S. manufacturing.

“What We Heard: America Invents Act”

Eagle Forum ELDF echoes grave concern over the problems NIST heard from RFI respondents regarding adverse changes to the U.S. patent system effected by the so-called “America Invents Act” and many judicial rulings, particularly by the U.S. Supreme Court. These have injected tremendous uncertainty and harm to patent owners with respect to patent-eligible subject matter, the grace period, the Patent Trial and Appeal Board and patent validity, loss of injunctive relief, open-ended opportunity to challenge patents, and the inability to secure damages against fraudulent or abusive challengers of patents (the integrity loophole). Each of these problems demand correcting, if the basis of technology transfer — secure, private intellectual property rights — is to achieve the goals NIST has set forth through this initiative.

These injurious measures require legislation to correct the problems arising from the AIA and the courts. The bipartisan STRONGER Patents Act, sponsored by Sens. Chris Coons (D-DE) and Tom Cotton (R-AR) and by Reps. Steve Stivers (R-OH) and Bill Foster (D-IL), and the bipartisan Restoring America's Leadership in Innovation Act, sponsored by Reps. Thomas Massie (R-KY) and Marcy Kaptur (D-OH), together would address most of the problems summarized in the Green Paper.

Government Use License

Clarifying, by regulations under the Bayh-Dole Act and the Stevenson-Wydler Act, the narrow scope of the government license to use transferred technology would strengthen the IP rights of those entities seeking to commercialize an invention. The government use license provisions would thereby be precluded from possibly serving as a back door to exactly the kind of encroachment on exclusivity these statutes intend to secure for patent owners and licensees of federally funded research discoveries. The regulations would clarify that government use license is only for government use of inventions it funds, not a short-cut for putting goods and services in commerce — undermining the ability to commercialize the technology through secure IP rights.

March-In Rights

Regulatory clarification under Bayh-Dole of the statute's march-in rights is badly needed, given the uncertainties injected by creative activists seeking to force change in the application of this emergency-only measure for extra-statutory purpose. Defining when march-in is appropriate, pursuant to statute, and clarifying the meaning of "reasonable terms" and "practical application" so as to definitively exclude price of goods and services — that is, to codify the original intent of the law's authors, as stated by Sens. Birch Bayh and Bob Dole — would safeguard the ability of commercializers to rely on the IP exclusivity that is critical to achieving commercial success and ensuring that private investors will continue to assume the risk involved in bringing an invention to market. March-in must never be twisted into a means of enacting price controls.

Preference for U.S. Manufacturing

We applaud the intended action to "Protect and strengthen the statutory requirement that products embodying or using federally funded inventions be manufactured substantially in the United States." The Bayh-Dole Act appropriately includes the requirement of domestic manufacture of transferred technology through exclusive licenses. This requirement bolsters the maintenance and expansion of a robust U.S. industrial base. We do not object to clarifying the statutory term "manufactured substantially in the United States."

We support streamlining the waiver process into a simple, uniform process applied across agencies, and we urge NIST to require agencies to respond to waiver requests expeditiously. But extending this waiver requirement to nonexclusive licensees and to contractors is problematic. The Bayh-Dole Act gives no statutory authority for applying this requirement to nonexclusive licenses. Requiring waivers for nonexclusive licenses adds another layer of complexity, and thus is a barrier to seeking such a license, where no problem appears to exist. After all, no U.S. manufacturer is blocked from making the transferred technology that is licensed nonexclusively. And adding a waiver requirement for nonexclusive licenses would seem counterproductive to the goal of streamlining in a business-friendly manner.

Further, Eagle Forum ELDF observes that waiving this statutory condition for exclusive licenses should be the exception, rather than the rule. The preference for U.S. manufacturing of transferred technology yields for the American public a fuller, more important benefit from taxpayer-funded research and development. This Bayh-Dole provision promotes the economic concept of a "virtuous circle," with Americans first working at good-paying industrial jobs where they produce things and empowered to spend some of their paychecks on the products that come from commercialized tech transfer efforts. The more incentives for companies to build production facilities in the United States, the more our industrial base grows, and the more supply chains are adjusted to use truly American manufacturers and produce truly American-made products. At the same time, Bayh-Dole is intended to move taxpayer-funded discoveries from concept to commercial use, which justifies a simple, consistent waiver when necessary.

Further, we reiterate the connection of economic competitiveness to our national security. The daily news reports of Chinese expropriation of U.S. IP, forced tech transfer and joint ventures in China, Chinese theft and espionage schemes that result in stolen sensitive U.S. information and Chinese agents proliferating throughout the United States demonstrate how true this is — and how serious the Chinese are about winning this competition for technological dominance. We appreciate the following from page 35 of the Green Paper:

> The September 2018 Department of Defense report to the President "Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States" in response to Executive Order 13806 makes the case for protecting American manufacturing. This report notes that it is imperative to maintain domestic manufacturing capability to meet more than current production needs with the conclusion that: "Above all, America's manufacturing and defense industrial base must support economic prosperity, be globally competitive, and have the capabilities and capacity to rapidly innovate and arm our military with the lethality and dominance necessary to prevail in any conflict."

Improved Partnership Mechanisms

Proposals for streamlining across agencies, through user-friendly, "speed-of-business-based" best practices for federal agency tech transfer processes and procedures, and enabling partnerships for translational R&D, technology maturation, and commercialization in existing partnership mechanisms (e.g., SBIR, CRADA) are generally consistent with what we had in mind in our RFI comments. Bringing consistency across the government for handover of intellectual property rights to collaborators, indemnification terms, and addressing the discrepancy in CRADA partnerships should improve the attractiveness for businesses to pursue technology transfer or licensing with federal agencies. At the same time, regulations to align federal tech transfer with Bayh-Dole standards may advance the goals, but a regulatory "one-size-fits-all" regime would jeopardize the appropriate flexibility needed to accommodate various technologies and licensing structures. The consistent licensing policies and practices of the federal government should constrain agencies from continuing to fail to be responsive, expeditious, and efficient in doing partnership deals and prioritizing tech transfer. It should not turn into more red tape that blocks private-sector interest.

The Green Paper proposals aim to improve business-customer friendliness that has been lacking in many federal labs and research agencies. We want reforms that promote the flourishing of innovation ecosystems across the nation, particularly where research institutions, federal laboratories, other federal and military facilities, and advanced manufacturing and advanced materials resources and businesses are located. The availability of a range of partnering vehicles, such as CRADAs, and SBIRs/STTRs, coupled with the use of a portion of R&D funding to secure IP protection, would help more IP-centered startups to gain traction and more early-stage firms to become going concerns faster. The key would be accountability of government actors with the existing mechanisms. This seems to be missing.

We are concerned about Intended Action 8, where it mischaracterizes royalties as promoting compliance with license terms. Royalties actually are payment for the license to use the technology. Thus, we urge dropping 8(E). First, Bayh-Dole regulation should not be issued in order to distort and harmfully change the understanding of royalties. Second, each technology, license, and licensee faces specific circumstances that affect the pace of commercialization and progress in achieving milestones. The beauty of Bayh-Dole, as is widely recognized, is its putting incentives such as royalties in the right place, where these payments reward inventors and researchers and fund additional research.

A major concern arises from Intended Action 9, which as proposed would undermine Bayh-Dole's effectiveness where it is working in universities and private contractor entities, while empowering each agency to end-run Bayh-Dole. The proposed 9(B) strikes us as counterproductive to the purpose of the ROI Initiative — bringing federal agency and lab tech transfer up to snuff with academic tech transfer. The proposed Research Transaction Authority (RTA) would effectively expand Other Transaction Authority (OTA) to virtually the entire government, as footnote 152 states. OTA is not compliant with Bayh-Dole, and by virtue of this being the model, similar concerns arise about the proposed RTA mechanism. OTA enables and thus encourages agencies with this authority to pursue their own end-runs to Bayh-Dole, including denying private-sector contractors the rights Bayh-Dole provides them. OTA already puts and RTA would put IP exclusivity for licensees and contractors at high risk, spreading uncertainty of being able to enjoy the fruits of their commercialization efforts and investments. They also undermine the fundamental goal of Bayh-Dole: establishing a uniform patent policy across all federal agencies. This proposal could end up being so harmful that it erases the beneficial effects of limiting march-in rights through the definition proposed in Intended Action 2. We strongly urge that Intended Action 9(B) be eliminated.

Federal Workforce Entrepreneurship Opportunities
Extending opportunities for federal R&D agency employees to gain training in entrepreneurship, modeled on programs such as I-Corps, and harmonizing a means for managing conflicts of interest patterned on successful university faculty models would give them a better appreciation for and insight into the mindset of the potential collaborators sitting across the desk seeking a tech transfer deal. Providing a job track for tech transfer for those who might enter from the private sector would bring in-house a perspective that would enhance federal tech transfer. At the same time, leadership within federal labs and agencies across the government must come to regard technology transfer as core to their agency's mission. We agree with the comment on page 78 of the Green Paper: "Commercialization performance at Federal Laboratories will continue to lag universities until laboratory leaders are

directed, funded, and incentivized to place greater emphasis on commercialization outcomes, including through accountability to meaningful metrics." Meaningful metrics tied to meaningful commercialization outcomes and further tied to performance reviews and ratings of both leadership and rank-and-file federal employees should be added to the several intended actions in this section.

Federal Innovation Asset Tools

Proposals to improve access to federal R&D assets, IP, etc., by upgrading federal R&D data reporting systems and reporting standards should be expected to facilitate better knowledge of and transfer of technology assets. Integrating standards and outcome-based metrics into assessing the performance of federal workers, much like the suggestion above for tech transfer results, seems necessary in order to affect behavior by federal employees in this regard. In addition, the proposals addressing the customer-facing portal for making cross-government R&D asset and IP information consistent, user-friendly, up-to-date, and user-friendly would provide a tremendous service, empowering the American public with information about potential intellectual assets for commercialization and thereby enabling many more tech transfer inquiries. At the same time, we echo and share concerns about the necessity of securing proprietary information and not disclosing confidential information about an invention during patent prosecution.

R&D Metrics

We agree that establishing appropriate metrics is important to gauging the tangible improvement of federal agency and lab technology transfer, as well as the return on investment to the taxpayer. We applaud that the Green Paper recommendation places R&D outcomes and R&D impacts above operational metrics. Too often, government overemphasizes process metrics and near-neglects the results achieved. Efficiency, timeliness, customer-service, and similar metrics are important, particularly so with a government function such as technology transfer, where the customer is typically a business (often a startup or early stage company) with constraints and demands and timeframes much less forgiving than the typical pace of government. Still, in measuring the ROI to the nation and its taxpayers, the outcomes and impact of R&D

count more to taxpayers, who should be able to expect their government to track how much intellectual property, startups, R&D partnerships, etc., their research dollars lead to. Even more important is R&D investment impact — new companies in business after 5 or 10 years, jobs created, commercial products or standard-setting technologies on the market, and the benefits to national security and industrial competitiveness for the United States. In terms of tracking global trends and competitiveness, apples-to-apples comparisons with the same kinds of impact metrics for other countries should be considered.

The Missing Ingredient: Oversight and Accountability

The one ingredient we would suggest adding is to establish high-level technology transfer oversight and accountability. The Reagan Administration successfully supervised the implementation of the landmark 1980s technology transfer laws by establishing a high-level office in the Department of Commerce that worked in close coordination with the White House. Much of the success of Bayh-Dole and Stevenson-Wydler owes to implementation subject to close oversight and an overseer with the clout to hold other federal departments, agencies, and laboratories accountable for technology transfer congruent with the statutory requirements. The office stopped a number of international agreements that threatened to give away rights to taxpayer-funded R&D. As good as the recommendations in the Green Paper are, they are unlikely to achieve all that they ought absent high-level oversight and the power to hold the rest of the government accountable for living up to the statutory standard of technology transfer being a priority of every entity of the federal government. NIST could fill this role. It would take the willingness to monitor and hold accountable other agencies and departments of the government when they stray from the statutory constraints of Bayh-Dole and Stevenson-Wydler.

* * *

Eagle Forum Education and Legal Defense Fund appreciates the opportunity to provide feedback on the NIST Green Paper. We commend NIST for proposals intended to improve practical returns on federal research, for streamlining the processes to transfer technology from federal research facilities in a business-friendly and IP-respectful manner, and for realizing America's potential economic and national security benefits. We support this initiative, with the few exceptions discussed above.

Respectfully submitted,

/s/ Andrew L. Schlafly

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Attachment: "Benefiting from Federal Research Funding: Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society," proceedings of a briefing sponsored by Eagle Forum ELDF, Oct. 18, 2018.

From: Gus Simiao
To: roi
Subject: Green Paper Feedback
Date: Wednesday, January 30, 2019 11:33:36 AM

To Whom this may concern,

I would like to provide one thought on the green paper. I did not have a chance to read the entire document so this comment may already be incorporated. My comment is related to the topic of increasing engagement with the private sector.

I am an entrepreneur with experience in licensing technologies from universities into a newly formed company (startup) to commercialize the technology. Recently I have sought to license technologies from the federal government by reaching out to the Navy Research Lab, Army Research Lab, and others.

What I have obtained from them is a very long list of technologies that have been patented. Some labs have their own websites while others work with TechLink a Montana State University website that lists several technologies from the federal government. In all cases I found myself swimming this sea of patents with not much more than a paragraph description of each technology.

Such limited information has made it difficult for me to identify technologies that might have commercial potential. I have also tried to connect with the technology transfer managers to further discuss the matter. In most cases I was directed back to the website that lists the technology. Another challenge is that I have limited access to the researches who are working on these projects. I have no way of identifying them or contacting them. Unlike universities where it is much easier to identify and connect with professors on topics of interest.

Being from the private sector, it is not immediately obvious to me how you might solve this problem of making it easier for entrepreneurs to access federal government research. One thought might be for you to benchmark best practices from the leading technology transfer universities.

I appreciate your constraints and challenges. I just thought I tell you my story as one data point to help inform your work. I do believe this initiative is very important and hope it will turn out to be a successful effort.

Thanks,

Gus Simiao

M: (734) 272-2290

On Mon, Jan 28, 2019 at 3:37 PM NIST Director <director@nist.gov> wrote:

> Dear Colleague:

The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) announced the release of a Draft Green Paper detailing steps to modernize the U.S. system of technology transfer and innovation for the 21st century on December 6, 2018 with a request for feedback by January 9, 2019. As you are aware, we had a lapse in appropriations that included the Department of Commerce and NIST. I am therefore extending the period to provide feedback through **February 5, 2019**, via roi@nist.gov.

NIST is striving to address comments prior to the expiration of the current Continuing Resolution on February 15, 2019. While we all anticipate that there will not be another lapse in appropriations on February 15th, we are trying to balance the timing with the need to take swift action. The NIST ROI website was open to receive comments and most people were able to download the document.

We are very grateful for those who were able to respond and for the thoughtful input we received. However, we also received a few requests to extend the feedback period and would like to try to accommodate as many views as possible, while also trying to complete this paper in a timely fashion.

Once again, I am grateful for your continuing engagement in this important endeavor.

Sincerely,

Walter G. Copan, Ph.D.

Under Secretary of Commerce for Standards and Technology

Director, National Institute of Standards and Technology

From: NIST Director
Sent: Thursday, December 6, 2018 2:21 PM
To: NIST Director <director@nist.gov>
Subject: Commerce's NIST Announces Actions to Stimulate Commercialization of Federally Funded R&D

Dear Colleague:

The U.S. Department of Commerce's National Institute of Standards and Technology (NIST) today announced the release of a Draft Green Paper detailing steps to modernize the U.S. system of technology transfer and innovation for the 21st century.

The United States spends more than any other nation on research and development (R&D) each year, investing over $150 billion in federally funded R&D alone. To ensure that investment reaps the largest commercial, economic, and national security returns possible, the President's Management Agenda (PMA) directed NIST to work with the White House Office of Science and Technology Policy to speed the transfer of federally funded R&D to the private sector. As part of the PMA's Lab-to-Market Cross Agency Priority (CAP) Goal, NIST launched the Return on Investment (ROI) Initiative for Unleashing American Innovation, which led to the draft green paper.

The draft green paper identifies 15 actions intended to stimulate the commercialization of federally funded R&D. Implementing these actions will increase the impact of federal R&D investment through agile partnerships that can create tremendous value for our society and economy. For example, granting reliable and predictable intellectual property rights for licensing and commercial development of federal research will also encourage innovation and more private sector investment in R&D. The actions are aligned with the five strategies in the PMA's Lab-To-Market CAP Goal: 1) identifying regulatory impediments and administrative improvements; 2) increasing engagement with private sector experts and investors; 3) building a more entrepreneurial R&D workforce; 4) supporting innovative tools and services for technology transfer; and 5) improving understanding of global science and technology.

The draft green paper was developed based on broad inputs from the public in response to a Request for Information published in the *Federal Register*, public meetings and multiple stakeholder engagement sessions, and extensive review of prior reports and studies related to federal R&D technology transfer. The green paper also incorporates input from key federal stakeholders, including the National Science and Technology Council's Lab-to-Market Subcommittee. The green paper is a discussion document, not a policy commitment or decision by the federal government. Implementation of actions that require specific policy, legislative or regulatory changes will be advanced through the appropriate formal process, including interagency review and public comment.

The draft green paper as well as the public comments received in response to the Request for Information and background information about the initiative are available on the NIST ROI website. NIST will consider additional feedback on the green paper received by January 9, 2019, via roi@nist.gov. A final version is expected in early 2019.

I am grateful to all stakeholders, especially those who submitted oral and written comments in response to the RFI and at ROI public forums throughout 2018, to the outstanding, dedicated team at NIST and the Office of Science and Technology Policy, to all the U.S. federal science and technology agencies represented in the National Science and Technology Council and its Lab-to-Market Subcommittee, and to the Science and Technology Policy Institute (STPI) for your many contributions thus far.

Thank you for your continuing engagement in helping to chart this important course of action for the Nation.

Sincerely,

Walter G. Copan, Ph.D.

Under Secretary of Commerce for Standards and Technology

Director, National Institute of Standards and Technology

Response to NIST's Green Paper Draft on "Return on Investment Initiative"

February 5, 2019

The Electronic Frontier Foundation, the American Library Association, the Association of College and Research Libraries, and the Association of Research Libraries submit these comments in response to NIST's draft Green Paper on the "Return on Investment Initiative" (December 2018).

We are organizations that defend the public interest in access to information. We write to express our concern about Section E of the draft Green Paper, in which NIST recommends making government-produced software copyrightable. That recommendation appears to be based on misconceptions about the realities of both copyright law and collaborative software development. Moreover, the draft Green Paper ignores the widely accepted and long-standing reasons why federal government works are not subject to copyright—reasons that far outweigh any marginal and speculative boost to technology transfer that changing the default might bring. NIST should remove this recommendation from the Green Paper.

A. U.S. Government Works Have Never Been Copyrightable

Since the very beginning of copyright in the U.S., the law has maintained a basic principle that copyright does not extend to works of the federal government. In its very first copyright-related decision, the Supreme Court held that there could be no copyright in judicial opinions.[1] Expounding on that decision, the Court noted that judges "receive from the public treasury a stated annual salary . . . and can themselves have no pecuniary interest or proprietorship, as against the public at large, in the fruits of their judicial labors."[2] Congress codified that principle in the Copyright Acts of 1909 and 1978.[3]

This tradition reflects a practical understanding that allowing copyright in government documents necessarily means conferring the right to limit public access to those documents, such as by requiring users to agree to a license and pay a fee.[4] The exclusion of federal government works from copyright, by contrast, preserves the public's legal ability to access to the workings of government. That, in turn, helps ensure that the benefits of taxpayer-funded work are shared broadly.

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[1] *Wheaton v. Peters*, 33 U.S. 591, 668 (1834).

[2] *Banks v. Manchester*, 128 U.S. 244, 253 (1888).

[3] 17 U.S.C. § 105.

[4] *Code Revision Comm'n for Gen. Assembly of Georgia v. Public.Resource.Org, Inc.*, 906 F.3d 1229, 1239–40 (11th Cir. 2018) ("[A]ny work of which the People are the constructive authors is intrinsically public domain material and is freely accessible to all so that no valid copyright can ever be held in it."); *Am. Soc'y for Testing & Materials, et al. v. Public.Resource.Org, Inc.*, 896 F.3d 437, 447 (D.C. Cir. 2018) (recognizing "a serious constitutional concern with permitting private ownership" of the text of government edicts).

This tradition also reflects the purpose of copyright, which is to provide an incentive for the creation of new artistic and scientific works.[5] The work of federal employees is funded by taxpayers, and does not require the additional incentive of a legal right to limit access to that work.

The exclusion of federal government works from copyright is also consistent with open government laws and policies. In 2018, the President signed into law the Foundations for Evidence-Based Policymaking Act of 2018, which requires federal agencies to make their "data asset[s]" available to the public "in an open format" whenever possible.[6] Likewise, a policy adopted by the White House Office of Management and Budget in 2016 called for government agencies to release software source code to the public.[7]

B. Copyright Misconceptions in the Green Paper

The draft Green Paper proposes an amendment to copyright law that would extend copyright to software written by federal government employees, breaking with the general prohibition on copyright in federal government works. The draft claims that doing so would spur transfer of valuable software to private firms. This conclusion appears to be based on several misconceptions.

First, the draft claims that the absence of copyright in government-written software causes a "lack of control over potentially sensitive code."[8] This is incorrect, because limiting access to "sensitive" materials is not a function of copyright law. When copyright holders bring infringement claims for the purpose of limiting access to newsworthy facts, or government materials, or to suppress criticism, courts permit the use to go forward under the fair use doctrine.[9] Other legal mechanisms including nondisclosure agreements and trade secret law are better suited to the job of limiting access to "sensitive code."

Second, the draft Green Paper misleadingly suggests that copyrighting government software can help "ensur[e] software code integrity and version control."[10] Deterring false statements about the provenance, integrity, authorship, or version of a software program are the domain of trademark and unfair competition law, not copyright. Many companies that permissively license the patents and copyrights in their software for royalty-free use by the general public nonetheless use trademark enforcement to maintain quality, integrity, and accurate labeling.[11] The Green Paper alludes to free and open source (FOSS) software licenses that leverage copyright to create a legal requirement to preserve identifying information on a software program,[12] but FOSS licenses are not the only way, much less the best way in this instance, to create such a requirement.

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[5] *See Harper & Row Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 558 (1985).

[6] Pub. Law No. 115-435 (2018), codified at 44 U.S.C. § 3502 *et seq.*

[7] Federal Source Code Policy, M-16-21, https://sourcecode.cio.gov/ (accessed February 2, 2019).

[8] Draft Green Paper at 40, *available at* https://www.nist.gov/sites/default/files/documents/2018/12/06/roi_initiative_draft_green_paper_nist_sp_1234.pdf.

[9] *Am. Soc'y for Testing & Materials, et al. v. Public.Resource.Org, Inc.*, 896 F.3d 437, 453 (D.C. Cir. 2018); *Katz v. Google Inc.*, 802 F.3d 1178, 1182 (11th Cir. 2015); *Swatch Grp. Mgmt. Servs. Ltd. v. Bloomberg L.P.*, 756 F.3d 73, 92 (2d Cir. 2014); *City of Inglewood v. Teixeira*, No. cv-15-0815-MWF, 2015 WL 5025839, at *12 (Aug 20, 2015).

[10] Draft Green Paper at 41.

Third, the Green Paper incorrectly states that "[t]here is a need for the legal right for government software works to be protected by copyright in order to grant public users an open source license that helps define the terms of use."[13] While the contributions of government employees cannot be copyrighted, a FOSS project that includes privately authored code may still be subject to copyright, which gives legal force to the FOSS license used, provided that the government contributions are not intended to create a work of joint authorship. There is, in short, no barrier to government employees participating in FOSS development. As for software projects that are entirely federal government works, while it is true that a FOSS license cannot be applied, the public domain status of the code accomplishes the core purpose of a FOSS license, which is to ensure that the code is free for re-use by others.

C. Any Benefit to Technology Transfer Is Outweighed by Harms to Transparency

The draft Green Paper makes no attempt to weigh the costs of a Section 105 carve-out against the alleged benefit to technology transfer. It should, because that balance tilts firmly against the proposal.

Turning first to the benefits, they are minimal. As the draft acknowledges, there are myriad other ways to deploy government-written software for commercial use. For example, contractual agreements can take the place of copyright for some uses.[14] And software written by *contractors* at the request of an agency, including prime contractors like the Department of Energy laboratories, is subject to copyright.

Besides these, there are other ways that companies can use and profit from government-authored software. One way is for a private company to revise and build on the software code it receives from an agency. An analogous circumstance is the Android mobile operating system, which is proprietary commercial software derived from the open source Linux operating system.[15] For government-authored code, while the original code remains in the public domain, privately offered revisions, updates, and expansions can nonetheless be copyrighted. Another way is for private companies to offer services related to the software, such as support and hosting.[16] In each of these models, a transfer of the agency's expertise with the software can be as valuable (or more) than a transfer of copyright. Agencies can participate in technology transfer and earn revenues through training and partnering with the private sector, even if the underlying code is in the public domain.

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[11] For example, Mozilla Inc. makes its source code available under an open source license, but also prohibits use of its trademarks on modified code. Mozilla Trademark Guidelines, https://www.mozilla.org/en-US/foundation/trademarks/policy/ (accessed Feb. 2, 2019). Wikipedia, a freely licensed encyclopedia, likewise limits use of its trademarks. Trademark Policy, https://foundation.wikimedia.org/wiki/Trademark_policy (accessed Feb. 2, 2019).

[12] *See, e.g.,* Apache License 2.0, https://www.apache.org/licenses/LICENSE-2.0.html (accessed February 2, 2019).

[13] Draft Green Paper at 41.

[14] Draft Green Paper at 40.

[15] Ryan Block, "Google is working on a mobile OS, and it's due out shortly," Engadget (Aug. 28, 2007), https://www.engadget.com/2007/08/28/google-is-working-on-a-mobile-os-and-its-due-out-shortly/.

On the other side of the ledger sits the harm to government transparency and public participation that will result from applying copyright to government works. Copyright claims by government bodies are often at odds with the principles of the Freedom of Information Act and other open records laws.[17] And using copyright to limit the distribution of government-authored work runs counter to the recently enacted Foundations for Evidence-Based Policymaking Act of 2018.[18] The line between software and data is often blurry. Applying copyright to government-authored software would create a perverse incentive to package government data in the form of software in order to limit its re-use. The GAO recognized this danger in its 1990 report on the issue, which is cited in the draft Green Paper.[19]

We recognize that some industry partners would prefer that agencies give them firm control over the use and distribution of government-authored software, and that they are willing to pay handsomely for this privilege. But copyright in government-authored software is not a requirement for technology transfer, and it would bring its own costs in the form of harm to government transparency. Section 105 of the Copyright Act represents Congress's sound judgment that government does not need the incentives of copyright law in order to do work in the public interest, and that conferring a private right to exclude the public from using that work is itself harmful.

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[16] Red Hat Inc. uses a similar business model, providing support for users of open source operating systems. *See* Red Hat Service & Support, https://www.redhat.com/en/services (accessed Feb. 2, 2019). IBM also has a significant business division devoted to open source support. Open Source at IBM, https://developer.ibm.com/open/?lnk=ushpv18ct5&lnk2=learn (accessed Feb. 2, 2019).

[17] *See, e.g.*, *County of Santa Clara v. Superior Court*, 170 Cal.App.4th 1301, 1326 (2009) (county government's financial interest in restricting access to GIS maps did not overcome the presumption of public accessibility of government records).

[18] Pub. Law No. 115-435 (2018), codified at 44 U.S.C. § 3502 *et seq.*

[19] GAO Report, "Copyright Law Constrains Commercialization of Some Federal Software," (June 1, 1990), https://www.gao.gov/assets/150/149097.pdf.

We agree with the conclusion of the draft Green Paper that "uniform policy and procedures"[20] relating to federally developed software are beneficial. We recommend, however, that the proposal to amend Section 105 of the Copyright Act be removed.

Respectfully submitted,

Electronic Frontier Foundation
American Library Association
Association of College and Research Libraries
Association of Research Libraries

Contact: Mitchell Stoltz
mitch@eff.org

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[20] Draft Green Paper at 42.

KAISER PERMANENTE®

January 9, 2019

Walter G. Copan, Ph.D.
Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 8930
Gaithersburg, MD 20899

Submitted electronically to: roi@nist.gov

Re: ***NIST Special Publication 1234 - Return on Investment Initiative for Unleashing American Innovation Draft Green Paper***

Dear Director Copan:

Kaiser Permanente[1] appreciates the opportunity to provide comments to the National Institute of Standards and Technology (NIST) on the Return on Investment Initiative Draft Green Paper. We commend NIST for its attention to promoting domestic innovation and facilitating returns on government investments in research and development. However, some proposals in the Green Paper would further empower pharmaceutical companies to reap exorbitant profits on products developed based on federally-funded research and overprotect existing inventions in a manner that actually discourages meaningful, new innovation. We strongly urge NIST to revisit Green Paper recommendations that would increase the pharmaceutical industry's ability to inappropriately prolong monopoly pricing through anticompetitive abuses of intellectual property incentives.

In addition to unleashing innovation, one of the goals of NIST's Return on Investment Initiative is to help maximize benefits realized by the American people from inventions developed using the billions of dollars spent every year on government-supported research. Unfortunately, drug prices have risen so high that they are threatening sustainable access to treatment, including for drugs financed in part by these investments. American patients do not receive a fair return on investment when they are forced to endure significant financial hardship to pay for drugs developed using their tax dollars.

Kaiser Permanente is concerned that some of the recommendations in the Green Paper—such as narrowing the government's rights related to inventions developed with federal funding and potential changes to *Inter Partes* Review—would further embolden the pharmaceutical industry to set outrageously high prices. In addition, by further empowering pharmaceutical companies to

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[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members. As the largest private integrated health care delivery system in the United States, the Kaiser Permanente Medical Care Program delivers care to more than 12.2 million members in eight states and the District of Columbia. We are committed to providing high-quality, affordable care and improving the health of our members and the communities we serve.

One Kaiser Plaza
Oakland, CA 94612

over-patent and "evergreen" existing products, some of NIST's recommendations would heighten financial incentives to make incremental changes of limited clinical value to existing products in lieu of the more meaningful innovation the Return on Investment Initiative hopes to facilitate.

If implemented, the Green Paper's recommendations may also undercut the Trump Administration's laudable goals in the Department of Health and Human Services' (HHS') *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.[2] President Trump and HHS Secretary Azar have repeatedly emphasized that lowering drug prices is one of the Administration's top priorities. Intellectual property incentives are key drivers of high drug prices because they provide pharmaceutical companies with monopolies that prevent competition from lower-cost generics. Thus, policies in the Green Paper that would prolong monopoly pricing for periods disproportionate to the value of patent-protected innovation would interfere with the Administration's broader drug pricing goals and should be re-evaluated.

Government Rights in Inventions Developed with Federal Funding

The federal government has a discrete and limited set of potential tools to lower drug prices. It has failed to apply some of those tools to date, which has contributed to the pharmaceutical industry's ability to increase prices to unsustainable levels, threatening patient access to drugs developed based on federally-funded research. Prescription drug spending is growing faster than any other part of the health care dollar.[3] Spending on ten breakthrough drugs alone is projected to cost the federal government $50 billion over a decade.[4] Between 2010 and 2015, prices for the 20 most commonly prescribed drugs under Medicare Part D increased at a rate ten times higher than inflation, with average increases of 12 percent each year. Twelve of the top 20 drugs experienced price increases of over 50 percent.[5] These startling statistics illustrate the need to give the government *more* tools to combat high drug prices, rather than removing or narrowing tools currently at their disposal.

With this context in mind, Kaiser Permanente cautions against policies that would further restrict potential mechanisms available to the government to lower prices, including by limiting the application of government use licenses and authorities to retain rights in patented inventions developed based on taxpayer-funded research. Given the magnitude of the public's investment in drug development, it is reasonable for the government to have remedies available to protect against private companies' efforts to exploit and restrict access to federally-funded inventions. Indeed, grants from the National Institutes of Health (NIH) led to the approval of 210 new drugs between

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[2] HHS. (May 2018). *American Patients First: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. Available at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[3] Altarum Institute. (September 2015). *Health Sector Economic Indicators: Insights from Monthly National Price Indices through July 2015*.

[4] Avalere Health. (June 2015). *The Future Cost of Innovation: An Analysis of the Impact of Breakthrough Therapies on Government Spending*. Available at: https://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1433526540_The_Future_Cost_of_Innovation_An_Analysis.pdf.

[5] *Manufactured Crisis: How Devastating Drug Price Increases are Harming America's Seniors*, Minority Office, U.S. Senate Homeland Security & Governmental Affairs Committee, available at: https://www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf.

2010 and 2016, investing over $100 billion of taxpayer money in those medicines.[6] When drugs developed using federal funding are priced so egregiously high that reasonable access is threatened, it may be appropriate for the government to use tools available under the *Stevenson-Wydler Act* and *Bayh-Dole Act* to ensure taxpayers realize a fair return on their investments.

As the Green Paper correctly notes, the *Bayh-Dole Act* attempts to ensure inventions developed using federally-funded research benefit the American people. Under current law, the government can facilitate competition by allowing additional manufacturers to market drugs developed using taxpayer-funded research when "necessary to alleviate health and safety needs which are not being reasonably satisfied"[7] or when the "practical application" of the patented product is threatened because the product is not "available to the public on reasonable terms."[8] Whether the statute provides authority to intervene when high prices jeopardize access to drugs developed based on federally-funded research is the subject of considerable debate and remains unsettled law. As a result, NIH has never used this authority. Thus, clarification about how the *Bayh-Dole Act* can be used to increase access to extremely expensive drugs may be helpful.

Rather than interpreting the *Bayh-Dole Act* in a manner that would help increase access to drugs developed based on taxpayer investments, the Green Paper would restrict this authority to circumstances when there is "a compelling national issue or declared national emergency" after other remedies have failed. It would also specifically prohibit use of the *Bayh-Dole Act* as a mechanism to lower drug prices. These proposed limitations are unnecessary in light of the rigorous standards that already must be met to use march-in rights and repeated acknowledgement by the federal government that this remedy should only be used in extraordinary circumstances. Rather than unleashing new innovation, the Green Paper recommendations would only impede opportunities available to the Trump Administration to facilitate more affordable access to drugs that are prohibitively expensive.

***Inter Partes* Review**

While updating the *America Invents Act* (AIA) is not the central focus of the Return on Investment Initiative, Kaiser Permanente has concerns about the suggestions for modifying *Inter Partes* Review (IPR) that NIST plans to communicate to the U.S. Patent and Trademark Office (USPTO). The IPR process creates a more efficient alternative to challenging patents through the courts by allowing poor-quality patents to be invalidated administratively. In the context of the pharmaceutical market, IPR complements processes available under the *Hatch-Waxman Act* that help facilitate more generic and biosimilar competition against brand drugs that are a significant cost burden to patients, taxpayers, the government, and the health care system as a whole. Growing trends of over-patenting in a manner that adds minimal innovation and clinical value for patients has created a strong need for efficient mechanisms, such as IPR, to challenge potentially invalid patents in the pharmaceutical market.

While Kaiser Permanente acknowledges the important role that patents play in incentivizing innovation, we are deeply concerned about the pharmaceutical industry's pervasive abuse of the patent system to protect high prices. The IPR recommendations NIST plans to share with USPTO must be evaluated within the larger context of how patent and other intellectual property incentives have actually been applied in the pharmaceutical market. Many companies have effectively extended monopoly power for their drugs far beyond the 20 years of protection intended under our patent laws, eroding the taxpayer's return on public investment. For example, top-selling drugs like Herceptin® and Rituxan® have potential monopoly spans of nearly 50 years[9], and Purdue Pharma protected its pricing power for OxyContin® by obtaining patent extensions 13 times before the original patent expired.[10] About 78 percent of drug-related patents are for drugs already on the market.[11] The fact that most patents filed by the pharmaceutical industry protect existing, rather than new, products raises questions about the extent to which these additional patents are unleashing the kind of meaningful innovation the Green Paper is hoping to foster.

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[6] Cleary, E. et al. (2018). Contribution of NIH Funding to New Drug Approvals 2010-2016. National Academy of Sciences. Available at: http://www.pnas.org/content/early/2018/02/06/1715368115.
[7] 35 USC § 203(a)(2).
[8] 35 USC § 201(f).

Efficiently weeding out weak patents is especially important when pharmaceutical companies use "evergreening" strategies to prolong monopoly pricing by making minor changes, often of negligible clinical value, that enable additional patents on existing drugs. For example, Revlimid®—a multiple myeloma drug that is Celgene's biggest revenue producer—has a potential patent lifespan of at least 40 years. Before the patent expired on Celgene's predecessor drug (Thalomid®), Celgene modified and patented changes to the product to turn it into Revlimid, which effectively restarted the clock on generic competition.[12] Revlimid's numerous patents now cover everything from methods of use, to various formulations, to the product distribution system needed to comply with Risk Evaluation and Mitigation Strategies (REMS) requirements, and more.[13] Humira® is another well-known example of extreme use of evergreening. AbbVie has applied for at least 247 patents on Humira®, over 100 of which the USPTO granted.[14] This web of overlapping patents, known as a "patent thicket" or "patent estate," makes it incredibly difficult for generic manufacturers to launch lower-cost versions of drugs. Other brand-name companies are now trying to replicate AbbVie's strategy, which is an alarming trend.[15]

IPR facilitates thoughtful and efficient review of evergreening patents, making it more difficult for pharmaceutical companies to use invalid patents to block generic competition for years. While a pharmaceutical patent case often exceeds 30 months in court, IPR takes 12 to 18 months and still allows review by a panel of expert patent law judges. Only a small percentage of enforceable patents are challenged under IPR, and the USPTO must first determine that there is a "reasonable likelihood" that at least one patent claim is invalid before IPR can commence.[16] Importantly, the U.S. Supreme Court recently upheld the IPR process, ruling that it does not violate Article III of the U.S. Constitution.[17] Thus, claims that IPR allows frivolous challenges or denies patent holders due process are without merit.

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[9] I-MAK. (2018). *Overpatented; Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*. Available at: http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

[10] Feldman, R. and Wang, C. (2018) *May Your Price be Evergreen*, University of California Hastings College of Law. Available at: file:///C:/Users/D727253/Downloads/SSRN-id3061567.pdf.

[11] *Id.*

[12] Kodjak, A. (May 2018). How a Drugmaker Gamed the System to Keep Generic Competition Away. *NPR*. Available at: https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[13] I-MAK. (October 2017). America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices. Available at: http://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf.

[14] I-MAK. (2018). *Overpatented; Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices*. Available at: http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

[15] Koons, C. (September 2017). This Shield of Patents Protects the World's Best-Selling Drug. *Bloomberg Businessweek*. Available at: https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.

Forcing IPR to adopt the more burdensome processes and standards used in federal court would delay access to more affordable generics for American patients, embolden the pharmaceutical industry to continue abusing the patent process, and violate congressional intent under the AIA to establish a more efficient alternative mechanism for patent review. Kaiser Permanente therefore strongly discourages NIST from recommending that USPTO make unnecessary changes to IPR that would increase the burden for challenging weak and potentially invalid patents, which would undermine both efforts to reduce high drug prices and unleash meaningful innovation.

* * *

Kaiser Permanente appreciates the opportunity to provide feedback in response to NIST's draft Green Paper. We would be pleased to discuss our experience with high drug prices further. If you have questions, please contact me (510.271.6835; anthony.barrueta@kp.org) or Polly Webster (202.216.1900; polly.f.webster@kp.org).

Sincerely,

Anthony A. Ba

Anthony A. Barrueta
Senior Vice President, Government Relations

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[16] Waxman, H. et al. (July 2018). Proposed CREATES Amendment could Impede the Availability of Affordable Generic Drugs. Commonwealth Fund. Available at: https://www.commonwealthfund.org/blog/2018/proposed-creates-amendment-could-impede-availability-affordable-generic-drugs.

[17] *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 584 U.S. __ , (2018); *SAS Institute Inc. v. Iancu*, 584 U.S. __ , (2018).

From: Karin Immergluck
To: roi
Subject: Greenpaper Feedback from Stanford University
Date: Wednesday, January 9, 2019 10:30:10 AM

Dear Dr. Copan,

On behalf of Stanford President Tessier-Lavigne and Stanford Vice Provost and Dean of Research Moler, I would like to complement the NIST ROI committee on preparing a thoughtful draft green paper. We are pleased that the draft report and its recommended actions took into account comments made by various universities and COGR. We anticipate that the intended actions, if implemented in a thoughtful manner, will provide new benefits to both national lab and university technology transfer, mainly in the form of streamlined government-required processes and increased resources for entrepreneurship and commercialization activities.

Sincerely,

Karin Immergluck, Ph.D.
Executive Director
Stanford University | Office of Technology Licensing

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Association of American Universities
Association of Public & Land-Grant Universities
ACE American Council on Education
autm
AAMC Tomorrow's Doctors, Tomorrow's Cures®
COGR Council On Governmental Relations An Association of Research Institutions

On July 27, 2018, several of our associations jointly submitted extensive comments on the NIST Request for Information (RFI) on *Federal Technology Transfer Authorities and Processes* (Docket No. 18022019-819-01). Our comments contained a series of recommendations corresponding to the four principal questions on which NIST requested comments in the RFI.

We were very pleased to see that in the draft "Green Paper" (NIST SP 1234) NIST has responded positively too many of our comments and recommendations. We particularly note the recommendations related to Strategy 1 in the L2M CAP goal of identifying regulatory impediments and administrative improvements and Strategy 4 on innovative tools and services. These recommendations, if implemented, will be very helpful for technology transfer at our member institutions. The report also recognizes the variations in federal agency technology transfer practices and differences in interpretation which long have been of concern to our member institutions. Streamlining of and greater uniformity in such practices and interpretations would facilitate the ability of our members to transfer discoveries and inventions for economic value creation and public benefit.

We strongly support most of the Intended Actions in the Green Paper, including defining the scope of the government use license and clarifying the proper statutory uses of the "march-in" rights provided by the Bayh-Dole Act; streamlining the waiver process for the U.S. manufacturing requirement and providing a single government-wide point of application; allowing for limited use of federal research funds for intellectual property protection; implementing harmonized government-wide requirements for managing conflicts of interest involving recipients of federal R&D funding; and establishing a modernized platform for reporting data on intellectual property resulting from federal R&D funding with consistent government-wide reporting requirements. These actions address serious concerns in the current system. If implemented, they would have a direct positive impact on technology transfer at our institutions.

We also support other Intended Actions, including; allowing funds from government grants to be used to support intellectual property protection; summarizing public comments on SBIR/STTR technology maturation and determining appropriate follow-up actions to enhance these programs; establishing and expanding government-wide technology entrepreneurship programs, such as the highly successful NSF I-Corps program; streamlining partnership agreements for collaborations with federal laboratories; and expanding the metrics that are used to evaluate success of federal R&D investments and their resulting social and economic impacts. These will strengthen U.S. technology transfer over the longer term. This also is the case with concerns that the Paper identifies with respect to the America Invents Act, including Patent Trial and Appeals Board Proceedings, the grace period, and the scope of patent eligible subject matter. We had discussed these concerns in our comments as well, and we support NIST's plan to refer these concerns to the U.S. Patent and Trademark Office (USPTO). We also note that NIST will refer the issue of the need for more flexibility in the use of SBIR/STTR funds to the Small Business Administration (SBA). We look forward to further discussions with USPTO and SBA on these important issues as part of the PMA reform process. Similarly, we appreciate that NIST will refer the suggestions received from us and others to appropriate policy-making bodies with regard to changes in the tax code and tax incentives.

We do have a few concerns with the Paper. First, the discussion of Partnership Intermediary Agreements (PIAs) and other technology partnership mechanisms in Strategy 2.C is somewhat confusing. It encompasses a wide range of activities and agreements that are not necessarily comparable, such as university research parks, open campuses, DOE Agreements for Commercializing Technology, etc. It is not clear if the establishment of new Research Transaction Authority (RTA) agreements is intended to supersede or replace these other arrangements or only to provide "modernized" CRADAs. Of particular concern is the recommendation that they be modeled after Other Transaction Authority (OTA) agreements. The Paper asserts that OTAs "offer greater speed, flexibility and accessibility in performing research," and recommends that OTA authority be extended to all agencies (footnote 152). We are not aware of empirical evidence to back up the assertion of the benefits of OTAs. Our institutions have found them somewhat troublesome and often requiring extensive negotiation.

The Paper also is confusing in regard to the recommendation that RTAs be "strictly limited to R&D and not for use in procurement or financial assistance actions." Performance of R&D for the government typically occurs under procurement or financial assistance mechanisms, and OTAs tend to be used currently in place of normal R&D funding mechanisms (i.e., contracts, grants or cooperative agreements). The Paper also suggests that RTAs should convey intellectual property rights consistent with the Bayh-Dole Act, but, in fact, agencies have used OTAs to circumvent normal Bayh-Dole rights. (As an example, the revised Other Transactions Guide recently released by DOD encourages non-Bayh-Dole rights negotiations). We do fully support the overall strategy to develop streamlined new partnership mechanisms. However, we urge NIST to better focus the discussion in this section and reconsider the OTA-related recommendations.

Many of the strategies and recommendations in the Paper pertain to government agencies and federal employees (e.g., copyright protections for "government works," federal employee invention rights, Stevenson-Wydler Act interpretation, and federal scientists' ability to engage in entrepreneurial activities). They appear well-considered and we have no particular comments. We note, though, that the Paper does not address rights in software inventions by federal contractors. As discussed in our previous comments, the government's approach is inconsistent. Clarifying guidance from NIST would be helpful.

In conclusion, as the Paper rightly observes, federal technology laws and activities have served the nation well over nearly four decades and continue to support innovation. The Bayh-Dole Act was transformational when enacted in 1980, and the results for U.S. economic and job growth are amply documented in the Paper. The basic structure remains strong, but we fully agree that the ability of our member institutions to transfer federally funded R&D to innovative products, processes and services for the American people would benefit from the clarifications specified in the Paper. Implementing the recommendations would help realize the PMA vision of enabling the government to adapt to changing needs. We look forward to continuing to work with NIST to achieve the L2M CAP Goal of improving the transfer of technologies resulting from federally funded R&D to the private sector to promote U.S. innovation, economic growth, and national security.

February 5, 2019

Walter G. Copan, Ph.D.
Under Secretary of Commerce for Standards and Technology
Director, National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Dear Under Secretary Copan,

Internet Association applauds the National Institute of Standards and Technology (NIST) for publishing its draft green paper on the Return on Investment Initiative for Unleashing American Innovation. We share NIST's goal of increasing innovation in the U.S. economy, and we appreciate the opportunity to provide additional comments to those we provided with other associations in a separate submission.

Internet Association's mission is to foster innovation, promote economic growth, and empower people through the free and open internet. The internet creates unprecedented benefits for society, and as the voice of the world's leading internet companies, we ensure stakeholders understand these benefits. Internet Association represents the interests of leading internet companies,[1] whose commitment to innovation is core to their success.

The draft green paper contains a section devoted to the implementation of the Leahy-Smith America Invents Act (AIA) entitled "What We Heard: America Invents Act." The green paper indicates that the feedback received on the AIA will be transmitted to the U.S. Patent and Trademark Office (USPTO). Unfortunately, the current draft reflects only the views of those critical of the implementation of the AIA. In these comments we hope to provide the perspective shared by a broad range of stakeholders, including many in the tech community that the AIA has been a great success and is not in need of significant changes. Specifically, we will address the success of the AIA's inter partes review (IPR) process and the positive impact of *Alice Corp. v. CLS Bank International* on subject matter eligibility and patent quality. We hope these views will be included in your green paper and transmitted to the USPTO.

Congress passed the AIA in 2011 because of a demonstrated and serious concern that the issuance of many invalid patents had harmed innovation, driven wasteful litigation, and eroded public confidence in the patent system. The USPTO has successfully implemented the congressional plan laid out in the AIA. Current Patent Trial and Appeal Board (PTAB) proceedings, including IPR, provide an effective and fair mechanism for administrative review of the patentability of patent claims post-issuance. These proceedings are now an essential tool for addressing the assertion of low-quality patents and improving general patent quality. The agency has implemented a mechanism for public challenges to patentability that is faster than the prior system of inter partes reexamination, more flexible than the court system, and ultimately more workable and efficient for patent owners and patent challengers than any prior mechanism.

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[1] "Our Members." Internet Association. Accessed February 01, 2019. https://internetassociation.org/our-members/.

Despite complaints from some quarters, the AIA proceedings have *not* been slanted against patent owners. The statistics published by the USPTO demonstrate this point. There were over 300,000 patents issued FY18.[2] In contrast, there were only 1,521 petitions for IPR filed in FY18, and the PTAB instituted a full proceeding on only 60% of those petitions.[3] Only 16.6% of all petitions filed since the enactment of AIA have resulted in Final Decision holding all instituted claims unpatentable.

In addition, appellate review of PTAB decisions demonstrate their accuracy. At the Federal Circuit, AIA decisions have been affirmed in full in more than 74% of all cases, while being reversed or vacated in full in under 13% of such cases.[4] This high affirmance rate further reflects the PTO's fair implementation of the congressional mandate in the AIA.

AIA implementation has improved the overall health of the patent system by removing problematic, low-quality patents while having no impact on the vast majority of patents. Changes to PTAB procedures should not diminish that achievement, which provides a significant benefit to innovation in the high-tech industry. Indeed, any revision of PTAB procedures should be done cautiously and in view of this great success.

Another success for the patent community was the Supreme Court's 2014 decision in *Alice*. This decision was a crucial step toward invalidating overbroad, non-technical patent claims, which are often the basis of abusive patent litigation. Broad claims often tie up the use of abstract ideas, granting a monopoly where no investment in R&D or other technological contribution has been made to society. When asserted, these patents tax companies that made the investment to develop and bring new products and services to market. In *Alice*, the Supreme Court clarified that patent claims that recite a non-technical abstract idea are not eligible for a patent simply because they describe using a computer or the internet.

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[2] Crouch, Dennis. "Patent Grants." Patently-O. July 31, 2018. Accessed February 01, 2019. https://patentlyo.com/patent/2018/07/patent-grants-2.html.

[3] *Trial Statistics IPR, PGR, CBM - Patent Trial and Appeal Board September 2018*. PDF. United States Patent and Trademark Office, September 30, 2018. https://www.uspto.gov/sites/default/files/documents/trial_statistics_20180930a.pdf.

[4] Seastrunk, David C., Daniel F. Klodowski, and Elliot C. Cook. "Federal Circuit PTAB Appeal Statistics – September 15, 2018." Finnegan, Henderson, Farabow, Garrett & Dunner, LLP. October 17, 2018. Accessed February 1, 2019. https://www.finnegan.com/en/insights/blogs/america-invents-act/federal-circuit-ptab-appeal-statistics-september-15-2018.html.

The effect of *Alice* and subsequent cases has been significant in preventing vague business method patents from weakening innovative markets. In fact, the large majority of the increase in Section 101 rejections since *Alice* is fueled by rejected business method patents.[5] These are exactly the patents the Supreme Court intended to invalidate: those without any technical improvements or innovations.

As the courts apply *Alice* to invalidate many low-quality, non-technical patent claims, judicial decisions have proven themselves a viable pathway for refining and clarifying the scope of patent-eligible subject matter.[6] The USPTO has also recently released updated guidance on the application of Section 101 in light of *Alice*. The ongoing work of the courts and the USPTO and the success of *Alice* in preventing low-quality non-technical patents precludes any need for significant reform or legislative action at this time.

We thank you for your efforts to explore ways to increase innovation. We support your goal and are grateful for the opportunity to comment. We ask that you include in the final green paper a more complete description of the views on AIA implementation. The internet economy suffers when low-quality patents are permitted to create waste, fuel litigation, and prevent innovation. The effect of IPR and *Alice* has been to increase patent quality and reduce harmful behavior, and no significant changes should be made to either at this time.

Internet Association would be happy to discuss these or any other patent-related issues with you going forward should NIST consider future engagement in this area.

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[5] Landau, Josh. "Increase In § 101 Rejections Due Almost Entirely To Rejected Business Methods." Patent Progress. December 06, 2018. Accessed February 01, 2019. https://www.patentprogress.org/2018/12/06/increase-in-§-101-rejections-due-almost-entirely-to-rejected-business-methods/.

[6] See *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016) (software claims directed to a specific improvement to the way computers operate is patentable) and *McRO, Inc. dba Planet Blue v. Bandai Namco Games America Inc.*, 120 USPQ2d 1091 (Fed. Cir. 2016) (software claims directed to a technological improvement over existing software animation techniques were patent eligible).

INDIANA UNIVERSITY
OFFICE OF THE VICE PRESIDENT
FOR RESEARCH

Indiana University is pleased to submit this response to the National Institute of Standards and Technology (NIST) Return on Investment Initiative Green Paper (NIST SP 1234).

Indiana University, the State of Indiana's oldest public university, enrolls more than 100,000 students each year at its flagship campus, located in Bloomington, and at six other campuses throughout the state. The IU School of Medicine, the only research-intensive medical school in the state, is housed on IU's Indianapolis campus.

IU is a long-time leader in technology transfer activities and has contributed to the disclosure of more than 2,900 inventions by IU researchers over the last 20 years. Additionally, IU's support has led to the filing of more than 4,300 global patent applications and the issuing of nearly 1,100 global patents over the last two decades. IU's tech transfer activities are carried out by the Innovation and Commercialization Office, which is located within the Office of the Vice President for Research.

Since 1986, federal funding at IU has resulted in more than 1,500 inventions, 1,800 patent applications, and 250 license agreements. Moreover, IU has launched 42 startup companies from federally funded research. Licensing highlights include advances in time of flight mass spectrometry, ion mobility spectrometry, metrics for optimizing clinical optical prescriptions, gene therapy, and therapeutics for prostate cancer and Hepatitis B.

Indiana University is a member of the Association of American Universities (AAU), the Association of Public and Land Grant Universities (APLU), the Council on Government Relations (COGR), and the Association of American Medical Colleges (AAMC). These associations have joined the American Council on Education (ACE) and AUTM on a response that is attached to this submission. IU strongly endorses the recommendations and concerns that are outlined in this document.

Bryan Hall 300 107 S. Indiana Avenue Bloomington, IN 47405 https://research.iu.edu/

From: James Love
To: roi
Subject: 30 USC 937
Date: Thursday, December 20, 2018 11:59:40 AM

Are you familiar with 30 USC 937

https://www.govinfo.gov/content/pkg/USCODE-1997-title30/html/USCODE-1997-title30-chap22-subchapIV-partC-sec937.htm

30 U.S.C.
United States Code, 1997 Edition
Title 30 - MINERAL LANDS AND MINING
CHAPTER 22 - MINE SAFETY AND HEALTH
SUBCHAPTER IV - BLACK LUNG BENEFITS
Part C - Claims for Benefits After December 31, 1973
Sec. 937 - Contracts and grants

Any grant made pursuant to this subsection shall be conditioned upon all information, uses, products, processes, patents, and other developments resulting from such research being available to the general public,

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James Love. Knowledge Ecology International
http://www.keionline.org
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KEI Comments Regarding the NIST Special Publication 1234 Draft Green Paper on Return on Public Investment

January 9, 2018

Introduction 1

Government Use License (Royalty-Free Right in Inventions) 3
- Intended Action 1. 4
- Consequence of Intended Action 1 5

March-in Rights 6
- Intended Action 2. 6
- Consequence of Intended Action 2 7

Commentary 8
- What is a “Compelling National Issue”? 8
- The Policy and Objective of the Bayh-Dole Act as Described in the Statute 8
- The Bayh-Dole Act Statutory Standards for March-in Rights 9
- Available to the Public on Reasonable Terms 10
- The Culture of Private Benefit from Public Funded Research 11

Increasing Interest in the Use of Royalty-free or March-in Rights in Federally-funded Biomedical Inventions 11
- Table 1: Examples of march-in and royalty-free cases 12
- Two potential march-in or royalty-free rights cases 14
- CRISPR and CAR T 14
- Relationship Between Royalty-free and March-in rights and 35 USC § 1498. 15

The Views of Senators Birch Bayh and Robert Dole 16
  - Bayh’s Views Shifted with Client’s Interests 17
  - Dole was a Spokesperson for Viagra, Employed by Pfizer and Representing other Corporate Clients 19

Introduction

In December 2018, the Department of Commerce National Institute of Standards (NIST) published NIST Special Publication 1234, “Return on Investment Initiative for Unleashing American Innovation,” as a draft Green Paper. According to the initial release (prior to the government shutdown), comments were due by January 9, 2019.

The publication was available from: https://doi.org/10.6028/NIST.SP.1234, but is currently offline due to the federal government shutdown.

The draft Green Paper is 135 pages long, with 313 footnotes, and 8 pages of references. On page 7, there is a "Summary of Intended Actions" which is divided into 5 strategies.

The initiative was launched after the April 19, 2018 "Unleashing American Innovation Symposium" in Washington, DC, and followed four public hearings and a request for comments noticed on May 1, 2018 (83 FR 19052). The initial comment period closed July 30, 2018.

What started out as a review of licensing practices by federal labs has become a broader attack on reasonable pricing obligations for drugs and other inventions, and on several measures designed to enhance the private returns on public investments in research and development (R&D).

While some of the proposals may be promising, others are designed to neuter safeguards written into the Bayh-Dole Act, and in particular, to protect companies that sell expensive drugs, vaccines, diagnostic tests and gene- and cell-treatments like chimeric antigen receptor T-cell (CAR T) therapies from obligations to ensure products are affordable and accessible.

Among the recommendations are proposals to modify statutes to extend copyright of software authored by federal employees,[1] raise the cap on the amount in royalties federal employees can earn to $0.5 million per year,[2] and implement other measures such as the adoption of "business-friendly intellectual property rights"[3] in licensing agreements. The paper also includes a number of proposals by "stakeholders" to modify U.S. patent law on everything from standards for patentability to the USPTO post-grant review of patent claims and the enforcement of injunctions for patent infringement, which would serve to overturn eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388.[4]

Among the appalling recommendations in the draft Green Paper are those that relate to three public interest safeguards in the Bayh-Dole Act, including:

1. The federal government's royalty-free right to inventions it funded, as mandated under 35 USC § 202 and 35 USC § 209;
2. March-in rights on federally-funded inventions, under 35 USC § 203; and
3. The obligation to bring federally-funded inventions to practical application, including in particular the requirement that the benefits of the inventions be made "available to the public on reasonable terms."

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[1] Pages 38-43.
[2] Pages 49-50.
[3] Page 61, on extending the provisions of the Agreement for Commercializing Technology (ACT).
[4] Page 26, See "What we heard: America Invents Act."

The draft Green Paper includes analysis that is in some cases factually incorrect, incomplete or out of context, and/or lacks balance, in order to justify the argument that the U.S. government should not use its rights in federally-funded inventions to ensure that biomedical products and services are reasonably priced, or to otherwise justify the expansion of private rights in publicly-funded inventions.

Our comments begin by reviewing the proposed changes in the regulations and policies relating to the use of the royalty-free and march-in rights in federally-funded patents, and the efforts to use regulations to narrow the statutory definition of "available to the public on reasonable terms."

Government Use License (Royalty-Free Right in Inventions)

The federal government currently has a royalty-free right to use any invention it funded, worldwide. The statutory obligations for retaining such rights include 35 USC § 202 and 35 USC § 209.

For example, in 35 USC § 202, "Disposition of rights," the Bayh-Dole Act states:

> (4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

There is a similar provision in 35 USC § 209, concerning federally-owned inventions.

Note that the statue ensures the government retains the right "to practice or have practiced for or on behalf of the United States" the federally-funded invention. This right is limited, but only in that the royalty-free right has be used "for or on behalf" of the United States.

The Green Paper *Intended Action 1* proposes policies and regulations to limit such rights.

Intended Action 1.

Define the scope of the "government use license" for use directly by the government—or a government contractor in the performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government. The scope of the government use license should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services.

A. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR EXTRAMURAL R&D PROGRAMS

Implement regulatory change under the Bayh-Dole Act to (i) update the definition of government use license and its use directly by the government—or a government contractor in the performance of an agreement with the government—for government purpose only and not for the use of a third party,43 and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.44

B. UPDATE DEFINITION OF GOVERNMENT USE LICENSE FOR INTRAMURAL AND PARTNERSHIP R&D PROGRAMS

Implement regulations under the Stevenson-Wydler Act/45/ (consistent with the Bayh-Dole regulatory change) to (i) update the definition of government use license and its use directly by the government for government purpose only and not for use by a third party, and (ii) clarify the appropriate processes and use of the government use right based on a consistent interpretation of the definition restricting its scope of use.

/footnote 42/ U.S. Government Accountability Office (GAO). 2003. "Agencies' Rights to Federally Sponsored Biomedical Inventions." https://www.gao.gov/new.items/d03536.pdf

/footnote 43/ Two regulatory changes suggested:

> * Insert new definition in 37 CFR 401.2: "The term government use is defined as use directly by the government for a government purpose and

the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included."

* Insert new language into existing standard patent rights clause in 37 CFR 401.14(b) "Allocation of Principal Rights" clause: "The government use license is restricted by the following conditions:

(A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract."

/footnote 44/ 37 CFR 401.14

/footnote 45/ Regulatory authority to implement the Stevenson-Wydler Act will require legislative change. The planned action is discussed under Strategy 1, Section G.

Consequence of Intended Action 1

The consequence of *Intended Action 1* would be that the government license would protect uses only when the government uses an invention "for its own consumption or practice for its own direct benefit"(emphasis added) and "to continue to perform research" but would prohibit the use of the license in cases where "the government is not procuring the goods or services for its own direct use or consumption through a contract."

The primary motivation for the proposal in *Intended Action 1* is to **limit** the use of the government's royalty-free right to provide the **public access to affordable versions** of patented drugs, vaccines, gene- and cell-treatments and other therapies and diagnostics that are based upon federally-funded patented inventions.

March-in Rights

There are 63 references to march-in rights in the draft Green Paper.

The proposals to narrow the use of march-in rights are set out in *Intended Action 2*.

Intended Action 2.

Define the circumstances under which the government may exercise march-in rights consistent with the uses of march-in specified in statute and not as a regulatory mechanism for the Federal Government to control the market price of goods and services.

A. DEFINE CIRCUMSTANCES UNDER WHICH MARCH-IN RIGHTS MAY BE EXERCISED

Implement regulatory change under the Bayh-Dole Act to make explicit that the use of march-in rights specified in statute is reserved for a compelling national issue or declared national emergency when other remedies have failed. When a Federal agency receives information that it believes might warrant march-in, regulation will require that the agency first conduct an informal consultation with the contractor, grantee, or licensee to understand the nature of the issue and consider other potential alternatives to remedy the concern. The agency will summarize the efforts made to correct the non-compliance when notifying the contractor or licensee if it intends to proceed with a potential march-in action.

B. CLARIFY AMBIGUITIES IN MARCH-IN RIGHTS PROCESSES AND TERMINOLOGY Implement regulatory change under the Bayh-Dole Act by specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Provide a clear and consistent definition for “reasonable terms” contained within the existing statutory definition of “practical application.” Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace but not as terms (i.e., price control mechanism) for consumer use. 59 , 60 Clarifications for “reasonable terms” and “practical application” should allow flexibility in crafting commercial or other terms in license agreements to achieve effective technology transfer.

/footnote 59/ 37 CFR 401.14(j) details the march-in rights in standard Bayh-Dole Act patent rights. The four enumerated circumstances that the government would elect to assert march-in rights are: 1) contractor has not taken or is not expected to take effective steps to achieve practical application of the subject invention, 2) there is a health or safety need which is not reasonably satisfied by contractor or its licensees, 3) there is a public use requirement specified by Federal regulations that are not reasonably satisfied by contractor or its licensee, and 4) march-in is necessary because of preference of U.S. manufacturing has not been met, a waiver was not granted or obtained, or licensee is in breach of such agreement. Suggested changes to the enumerated circumstances may include language that makes clear that march-in will not be used for anti-competitive reasons such as price control. 37 CFR 401.6 details the procedures that govern the exercise of march-in rights. Language may be added to this section to provide procedural guidance regarding march-in right proceedings, fact finding, and determination.

/footnote 60/ 37 CFR 401.2 is the definitions section for Bayh-Dole Act rights regulation. The current definition of practical application, per 401.2(e), is "The term practical application means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being used and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms." The bolded text has been used to support the use of march-in rights as a price control mechanisms as reasonable terms has been interpreted to mean "low price."

Consequence of Intended Action 2

One of the proposed actions in *Intended Action 2* is to limit the circumstances in which a march-in can be used to situations where there is "a compelling national issue or declared national emergency when other remedies have failed." This is a higher standard than set out in the statue, and presents issues that a rights holder can litigate, making it all the more difficult to use march-in rights.

Another proposed action is to issue regulations that greatly narrow the definition of "available to the public on reasonable terms" (emphasis added). Specially, the draft Green paper would require statements:

> specifying that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services. Provide a clear and consistent definition for "reasonable terms" contained within the existing statutory definition of "practical application." Clarify the intent of reasonable licensing terms to allow a product or service to reach the marketplace **but not** as terms (i.e., price control mechanism) **for consumer use**. (emphasis added)

Commentary

What is a "Compelling National Issue"?

The draft proposal would limit march-in cases to a "compelling national issue or declared national emergency."

Unless a "declared national emergency" can fail to qualify as a "compelling national issue," the reference to a declared national emergency seems either unnecessary, or designed to color the standard in a way that will narrow the use of march-in rights.

Ultimately, what the Green Paper proposes is to eliminate the use of march-in rights when there are abuses of patent rights, unless such abuses meet some vague standard of being a "compelling national issue." The new standard is vague and invites litigation, for example:

- Are unreasonable prices for biomedical inventions "a compelling national issue"?
- Is a specific overpriced drug or cell therapy for breast cancer a "compelling national issue"?
- Was a shortage of Fabrazyme, which was a personal tragedy for patients, a "compelling national issue"?
- If the NIH threatens to use march-in rights if patent holders don't have more liberal licensing terms for upstream uses of patents on stem cells or CRISPR inventions, does that meet the "compelling national issue" standard?

The Policy and Objective of the Bayh-Dole Act as Described in the Statute

The Bayh-Dole statutes give a much broader mandate for the use of the royalty-free or march-in rights. The "Policy and objective" of the Act is set out in 35 U.S. Code § 200, and includes this mandate:

> It is the policy and objective of the Congress . . to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; (emphasis added)

The Bayh-Dole Act Statutory Standards for March-in Rights

The specific grounds for using the march-in rights do not require extreme tests, or meeting the proposed and vague status of "compelling national issue." On the contrary, they are fairly straight forward:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

The problem today is not that agencies use the march-in rights too frequently, but rather on the contrary, that the rights are rarely invoked, despite cases where there is a clear abuse of patent rights.

In January 2016, 51 members of Congress wrote to HHS Secretary Sylvia Mathews Burwell and NIH Director Francis S. Collins (copy at https://www.keionline.org/22983) urging both "to utilize your existing statutory authority to respond to the soaring cost of pharmaceuticals," noting:

> When declining to exercise these march-in rights in response to previous petitions, NIH has suggested that controlling drug costs is a legislative duty. While that is accurate, Congress legislated long ago on a bipartisan basis in delegating authority to federal agencies such as NIH the responsibility to address one aspect of this problem. We call upon you to do that job. The failure to act in the past has undoubtedly sent an unfortunate signal that prices for federally-funded inventions can be set as high as a sick

> or dying consumer will pay. In 2013, for example, NIH rejected a request to issue rules related to pricing disparities between the United States and other high-income countries. While this may not be the sole standard considered, it exemplifies the type of standard which could be set.

In the Senate report to accompany the National Defense Authorization Act for Fiscal Year 2018, the Senate Committee on Armed Services sought to remedy this for a different funding agency by providing a directive to the Department of Defense:[5]

> **Licensing of federally owned medical inventions**
> The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

Both the 2016 Congressional letter and the 2017 National Defense Authorization directive focused on a particular rule that could be invoked to protect U.S. residents from unreasonable prices, namely that U.S. residents should not pay more than residents of other high income countries for drugs where public funds were used for the patented inventions. The 2016 Congressional letter and the 2017 directive to the DoD were motivated by public debate on the problem of high drug prices, which is certainly a "compelling national issue."

Available to the Public on Reasonable Terms

The draft Green Paper seeks to narrow the meaning of the statutory requirement to make the benefits of inventions "available to the public on reasonable terms." This obligation is found in the statutory definition of "practical application", in 35 USC § 201(f) of the Bayh-Dole Act, which reads as follows:

> (f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms. (emphasis added)

Dr. Francis Collins and before him Elias A. Zerhouni, M.D both have taken the position that obligation to make the benefits of inventions "available to the public on reasonable terms" will be satisfied if a company makes a product "available to the public at any price." This is a tortured interpretation of “available to the public on reasonable terms”. Price is the term that counts the most for “the public.” What other terms do NIST experts think the public is concerned about?

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[5] 115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, on page 173

The Culture of Private Benefit from Public Funded Research

The culture at the NIH is to ignore concerns the public has over the pricing of products. NIH scientists themselves are often named as inventors on patents, and under current law, are able to receive as much as $150,000 per year in royalties on such inventions, while employed by the NIH, in addition to whatever salary they earn. The Green Paper is proposing increasing the royalty cap to $0.5 million per year for all federal employees.

In 2016, KEI requested from the NIH records on royalty payments to its employees. The NIH has yet to provide such information.

Federal employees also often leave the government and join biomedical companies, large and small. There is an extensive revolving door, from the government and government-funded research institutions to private industry, and sometimes back to government or non-profit research jobs.

For example, until April 2018, Dr. Zerhouni was the President for Global Research and Development at the French pharmaceutical company Sanofi. Charles Sawyers, MD, from Sloan Kettering, is the principal investigator for more than $26 million in NIH grants from 1990 to 2018, including $5 million for 2017-2018 fiscal years. He has also advised the U.S. Army on prostate cancer research, co-founded biotechnology companies, and holds a seat on the Novartis Board of Directors, while working with Vice President Biden and NIH Director Francis Collins on the Cancer Moonshot. It is not surprising that many NIH-funded researchers support policies on government-funded research that provide huge benefits to private interests.

Increasing Interest in the Use of Royalty-free or March-in Rights in Federally-funded Biomedical Inventions

In general, federal agencies have been reluctant to use the government’s royalty-free rights or the funding agency’s march-in rights in federally-funded inventions. That said, such rights have been used in the past, and there is increasing interest in such use going forward.

Table 1 provides a list of notable cases where various federal agencies have considered or been asked to consider the use of royalty-free or march-in rights to address issues of drug pricing and affordability, shortages of products, or use of technologies to create new biomedical products, involving the NIH, the CDC, DOE and the U.S. Army.

Table 1: Examples of march-in and royalty-free cases

Type	Year	Invention/product	Petitioner or intended petitioner, and outcome
March-in	1997	Ceprate SC, bone marrow transplantation	CellPro v Johns Hopkins, Link Outcome: CellPro was able to stay an injunction until a competing product was FDA approved, benefiting CellPro and patients using the CellPro device, but CellPro ultimately failed to obtain a license. Of note: Former Senator Birch Bayh represented Cellpro, and argued that John Hopkins University's demand for high royalties would lead to high prices and that high prices would have a negative impact on patients.
March-in	1999	Fluorescent in situ hybridization tests	Ventana Medical Systems (now owned by Roche) *v* the University of California. Outcome: DOE had funded the technology. After a 30-month fact-finding process determination by DOE, Ventana was able to obtain a license and marketed a FISH test in competition with Vysis, a subsidiary of Abbott laboratories.
Royalty-free	1999	Several drugs	Ralph Nader, CPTech and Essential Action, Link Outcome: NIH Director Dr. Harold Varmus rejected the request to allow the World Health Organization (WHO) to use the U.S. government's royalty-free rights in drug patents in low income countries.
March-in/royalty-fr	2001	Stem cells	WARF

ee (threat)			Outcome: NIH negotiated two agreements with WARF on licensing stem cell patents.
March-in	2004	Norvir/ritonavir	Essential Inventions v Abbott, Link Outcome: NIH rejected the march-in request, but only after Abbott agreed to roll back a 400 percent price hike for patients on federal programs.
March-in	2004	Latanoprost	Essential Inventions v Pfizer, Link Outcome: NIH rejected the march-in request.
March-in (threat)	2006	Reverse genetics for avian flu	Centers for Disease Control Outcome: More liberal licensing of reverse genetics patents.
Royalty-free	2007	Stavudine/d4T and ritonavir	Essential Inventions, Link Outcome: OMB head Robert Porter rejected the request to use the federal royalty-free rights.
March-in	2010	Fabrazyme shortage	Joseph M. Carik, Anita Hochendoner, and Anita Bova v Mount Sinai School of Medicine of New York University/Sanofi/Genzyme, Link Outcome: The NIH prevented Genzyme/Sanofi from enforcing an injunction against Shire in Germany until Sanofi restored manufacturing capacity.
March-in, royalty-free	2012	Ritonavir and other drugs	American Medical Students Association (AMSA), Knowledge Ecology International (KEI), U.S. Public Interest Research Group (PIRG) and the Universities Allied for Essential Medicines (UAEM), Link Outcome: NIH rejected march-in request.

March-in, royalty-free	2016	Xtandi (enzalutamide)	Knowledge Ecology International (KEI) and the Union for Affordable Cancer Treatment (UACT) v University of California/Astellas, Link Outcome: NIH rejected march-in request andU.S. Army rejected march-in request.
March-in, royalty-free	2017	Zinbryta (daclizumab)	Knowledge Ecology International (KEI), Link Outcome: Product withdrawn from market.
March-in/royalty free right (ongoing campaign)	2018	Truvada (emtricitabine/tenofovir disoproxil fumarate)	PrEP4All v Gilead Outcome: Ongoing. HHS has not yet acted.

Two potential march-in or royalty-free rights cases

The following are two cases where the use of royalty-free or march-in rights are under active consideration, and which would be prejudiced by the proposed changes in *Intended Actions 1* and *2.*

1. Spinraza/nu. The high price of Spinraza ($750,000 for first year of treatment, and $375,000 for maintenance) has created restrictions on access to this treatment for spinal muscular atrophy (SMA) a neuromuscular disorder that harms children. The price for this treatment, invented at the University of Massachusetts and Cold Spring Harbor on NIH grants is reportedly less than $100,000 per year in some European countries.
2. Xtandi/enzalutamide. A veteran is expected to petition the Department of Defense to use its Bayh-Dole rights to enable competition for enzalutamide, a drug for prostate cancer invented on a grant from the U.S. Army that has an average wholesale price of $159,000 per year in the United States, and a much lower price in other high income countries. This petition will ask DoD to apply the 2017 DoD authorization directive described above.

CRISPR and CAR T

Extensive patent thickets are emerging in CRISPR and CAR T technologies, two promising areas of biomedical innovation.

On June 6, 2017, Knowledge Ecology International wrote to the U.S. Department of Health and Human Services (DHHS) asking the Department to adopt a policy on the licensing of federally-funded CRISPR patented inventions (link here). The NIH has declined to do so, but at a future date, under different leadership, may revisit this issue.

CAR T-Cell therapies are also plagued with extensive patent filings and overlapping claims, leading to considerable litigation, high costs for acquiring intellectual property rights and legal-related business risks.

For both CRISPR and CAR T, the NIH has played a key role in funding the most important and foundational innovations, and can use the royalty-free and march-in rights to pressure rights holders to more liberally license platform patents.

Relationship Between Royalty-free and March-in rights and 35 USC § 1498.

35 USC §1498(a) "Patent and copyright cases," provides for a limitation on the remedies for nonvoluntary government use of patented inventions. Injunctions are not available, but patent holders are entitled to compensation, which is set by courts. Proposals have been made since 2001 to use §1498(a) to obtain low cost generic versions of a variety of drugs, including in 2001 CIPRO/ciprofloxacin, in 2005-6 Tamiflu/oseltamivir, in 2006 Avastin/Bevacizumab, in 2014-2018 sofosbuvir-based HCV drugs, and in 2016-2018, various anti-overdose remedies. (See: https://www.keionline.org/cl/28usc1498). A constant objection from federal agencies is the risk of a costly compensation obligation, by a federal court.

In the ritonavir march-in cases, the NIH expressed concern that a march-in license on the federally-funded inventions would not be sufficient, if other non-federally-funded patents were infringed.

The Section 202 and 209 government use license can mitigate the risks of large judgements for non-voluntary use of patents, and Section 1498 can mitigate the problem of not having access to all relevant patents under march-in. Taken together, Section 1498 can clear out any evergreening patents that may present issues, and the Section 202 or 209 licenses can eliminate the risk of large compensation judgements. The draft Green paper would limit the ability of the federal government to take advantage of these opportunities where there is a clear need to remedy an excessive price.

The 202 and 209 licenses can also be used to register drugs, as noted by Alfred Engelberg and Aaron Kesselheim in a 2016 article in Nature Medicine.[6]

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[6] "Use the Bayh-Dole Act to lower drug prices for government healthcare programs," Nature Medicine 22, 576 (2016) doi:10.1038/nm0616-576, Published online 07 June 2016.

Hatch-Waxman requires a manufacturer that is seeking approval to sell a generic copy of a patented new drug like enzalutamide to certify that any patents on the new drug are invalid or will not be infringed. This requirement may seem to prevent a generic manufacturer that has no basis for substantively challenging enzalutamide's patents from obtaining FDA approval before the patents expire. But because of the government's Section 202 license, we believe that a generic manufacturer could certify that the patents will not be infringed because approval is being sought for the sole purpose producing enzalutamide for sale to the government. Any suit claiming infringement of the enzalutamide patents despite such a certification should be dismissed by a federal court, because law /fn3/ prohibits the court from interfering with the right of a government supplier to bid on or participate in the sale of products to the government, irrespective of the existence of patents. /fn4/ The only available course of action for acts of patent infringement by or for the government is to initiate a suit in the US Court of Federal Claims—but the Section 202 license would provide the government with a complete defense.
fn3/ 28 USC 1498(a)
fn4/ Gore v. Garlock, 842 F.2d 1275, 1282 (Fed. Cir. 1988).

The Views of Senators Birch Bayh and Robert Dole

The draft Green Paper quotes former U.S. Senators Bayh and Dole to support the notion that march-in was not intended to address pricing issues.

This deserves some commentary. First, this is how the Green Paper presented the views of Senators Bayh and Dole:

> The original sponsors of the Bayh-Dole Act have noted that their intent was to ensure that products were licensed for reasonable terms rather than being used as a price control. (Refer to "Statements by Senators Bayh and Dole on March-In.")
>
> > **Statements by Senators Bayh and Dole on March-In**
> > The "Bayh-Dole [Act] did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that

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http://www.nature.com/nm/journal/v22/n6/abs/nm0616-576.html

> should be dictated by the government...The ability of the government to revoke a license granted under the [Act] is not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from [federally] funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product," among other circumstances.
>
> Source: Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002.

The Green Paper quotes a letter to the editor by Bayh and Dole[7], responding to an op-ed and earlier academic article by Professors Peter Arno and Michael Davis.[8]

Bayh's Views Shifted with Client's Interests

Bayh would later repeat this argument in the 2004 hearing on ritonavir march-in petition, in support of Abbott. At the 2004 hearing, Bayh claimed that no one had paid him to testify at the hearing. What he neglected to disclose, was that he was a partner in a firm representing Abbott. Moreover, Bayh neglected to note that in 1997, he represented Cellpro in a march-in request, and made the contrary argument.

> In enacting Bayh-Dole, Congress made the judgment that policy objectives of commercializing the results of federally-funded research were better served by allowing federal nonprofit grantee institutions like Johns Hopkins to obtain and hold patent rights, with exploitation of inventions generally left to the nonprofits' licensing programs and competitive forces. At the same time, however, Congress recognized that in particular cases the public interest might require government action and therefore included in the Act 'march-in' provisions "to ensure that the

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[7] Letter to the editor, Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, April 11, 2002, page A28.

[8] Peter Arno & Michael Davis, Paying Twice For the Same Drugs, *Washington Post*, March 27, 2002, page A21; summarizing their earlier academic article, Peter Arno & Michael Davis, (2001) Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research, 75 TULANE L. REV. 631.

Government obtains sufficient rights in federally supported inventions to . . . protect the public against nonuse or unreasonable use of inventions." . . .

To carry out these federal policies, the Bayh-Dole Act provides that a Federal agency may exercise its march-in rights and require the exclusive licensee of an invention made with Federal funds to issue a license to a responsible applicant's "upon terms that are reasonable under the circumstances" if the Federal agency determines that

> (a) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; [or]
>
> (b) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees. 35 U.S.C. 203.

In the present instance, both of these statutory bases have plainly been met.

. . .

In fact, the circumstances — and the interests of the public which paid for the research that led to the patents and is now being asked to pay again — cry out for a far lower royalty payment by CellPro.

. . .

CellPro submits that there may well be reason for the government to adopt regulations covering situations like the present where the same product may be claimed to be covered by patents arising out of work done by more than one federal grantee. Moreover, investigation may be needed to determine whether the royalty layering that plainly exists in the present case . . . is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation.

Source: The March 3, 1997 march-in petition to Secretary Donna E. Shalala from Lloyd Cutler and Birch Bayh, on behalf of Cellpro. (Copy here).

Bayh's views, set out in an amicus brief, on what the Bayh-Dole Act required regarding the ownership of federally funded inventions, was rejected by the U.S. Supreme Court in *Stanford University v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011), illustrating the risks of relying upon the recollections and opinions of former members of Congress, as regards the intent of a U.S. statute.

Dole was a Spokesperson for Viagra, Employed by Pfizer and Representing other Corporate Clients

Upon leaving the U.S. Senate, Dole joined Verner, Liipfert, Bernhard, McPherson and Hand, as a lobbyist. In 2003, after Verner, Liipfert was acquired by Piper Rudnick, Dole joined the Washington, D.C. law and lobbying firm Alston & Bird LLP.

By the time Dole co-signed the letter with Bayh, he was working for Pfizer. Dole began doing television commercials for Pfizer in 1998.[9]

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[9] Pfizer Hires Bob Dole for TV Ad Campaign, December 12, 1998, Associated Press. http://articles.latimes.com/1998/dec/12/business/fi-53139

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MP190016

January 8, 2019

Response of the MITRE Corporation to the NIST RFC on the ROI initiative Green Paper (Draft NIST Special Publication 1234)

For additional information about this response, please contact:

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The MITRE Corporation is happy to have the opportunity to review and provide comments on the draft Green Paper. As a not-for-profit, public interest company, we operate seven federally funded research and development centers (FFRDCs) and perform independent research to address public sector challenges. We believe that transitioning technology into the private sector is a critical part of our public interest charter and we routinely do so. Maximizing the impact of these transitions is both a corporate and a national goal.

While reviewing the draft Green Paper, we were not only pleased to see that our prior recommendations had been incorporated but were also impressed by the organization, depth, and outcome-focused nature of the document. The result is an outstanding assessment and description of status, background, and necessary actions – for individual issues as well as for the return on investment (ROI) initiative overall. The document is a good step toward meeting the lab-to-market Cross-Agency Priority goal, and we applaud the interagency's efforts.

After reviewing the document, MITRE has developed the following recommendations we believe will further enhance the impact of the Green Paper:

- ***Strategy 1, Government Use License:*** Bayh-Dole and Stevenson-Wydler provide intellectual property rights to nonprofits, yet some federal agencies attempt to impose restrictions on the ability of nonprofits to assert patent rights or copyright for other than journal articles. Emphasis must be made to communicate to federal agencies the need to provide these rights to nonprofits and to not impose restrictions as a part of the contract negotiation process.
- ***Strategy 1, Software Copyright:*** The document should note that software development processes are changing, with modern software delivery best practices likely to complicate the software copyright issue even further[1]. The Air Force's Kessel Run approach would be a good exemplar for a test analysis.[2]
- ***Strategy 2:*** The U.S. government should consider participating more actively in international standards-setting organizations, as these often set parameters for technologies that will soon be commercially available. By better understanding what is potentially available (from government-developed capabilities), these bodies will be able to create standards that more readily enable future innovations to come to fruition. For example, 5G internet will result in a new, global cyber ecosystem. The extent to which it creates transparent and competitive environments for new information technologies depends on the standards and architecture that will be adopted.
- ***Strategy 3:*** While the discussion on technology entrepreneurship programs is well developed, a wider viewpoint is also needed if we are to meet the goal of developing a more entrepreneurial mind-set within federal researchers. What can be done with traditional incentives (such as student loans, research dollars, data access, and training programs) and with expanded and more strategic use of the Intergovernmental Personnel Act and other means? The U.S. is not the only country investigating this issue, so we should study other countries' research and development cultures to see how their approaches could be applied here.[3]

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[1] For example: software that combines open-source and specifically-developed code, leveraging libraries of codes with differing IP agreements, and the growing practice of multiple parties collaboratively developing code.

[2] https://kesselrun.af.mil/

[3] For example, China's approach to identifying and developing strategic markets is providing technology entrepreneurs (from around the world) with ambitious goals and a framework that enables their investments to

- ***Strategy 5***: Enhanced public-private collaboration is required to better understand global science and technology trends and benchmarks. Existing stovepiped analysis efforts should be integrated, with additional assets brought into the fold, such as the National Intelligence Officer for Science and Technology (to collect and analyze information on the competitiveness of foreign technology developments) and the National Academy of Sciences (which is a proven resource in convening government, academic, industry, and other experts, and can lead workshops that focus on global and technology-specific trends).

Please don't hesitate to reach out if you have any questions or comments. We appreciate the opportunity to provide our input and we applaud your work to date on this thoughtful paper. We would welcome an opportunity to meet to discuss the paper and our additional input in detail if you are interested.

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have impact — and is reportedly further reinforced with government grant funding. As a result, China is moving beyond the U.S. in fusion energy and may achieve practical quantum communication and large-scale implementation of artificial intelligence in advance of the U.S.

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Doctors Without Borders/Médecins Sans Frontières Comments to NIST Special Publication 1234: *Return on Investment Initiative for Unleashing American Innovation*

January 9, 2019

Doctors Without Borders/Médecins Sans Frontières USA (MSF) provides the following comments regarding the report issued by the National Institute of Standards and Technology, "NIST Special Publication 1234: Return on Investment Initiative for Unleashing American Innovation," (December 2018).

MSF is an international medical humanitarian organization providing care to people affected by armed conflicts, epidemics, natural disasters and exclusion from healthcare. In 2017 we worked in 72 countries. Among other healthcare activities, MSF provided more than 10 million outpatient consultations, treated 2.5 million cases of malaria, and administered millions of doses of vaccines and immunological products.[1] To do this work we rely on biomedical innovations that improve medical outcomes and are accessible and affordable.

We write to request that the National Institute of Standards and Technology (NIST) extend the deadline for the comment period on this report. Many links on the NIST website, including for Special Publication 1234 currently redirect to the homepage,[2] which bears the following notice: "NOTICE: Due to a lapse in government funding, this and almost all NIST-affiliated websites will be unavailable until further notice. Learn more NIST websites for programs using non-appropriated funds (NVLAP and PSCR) or those that are excepted from the shutdown (such as NVD) will continue to be available and updated." We are concerned that this will have negatively impacted stakeholders' ability to adequately review the report and any potential additionally relevant materials, such as documents, transcripts or information from past meetings and requests for information referenced in the report and related to this initiative.

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[1] For more information see: https://www.msf.org/international-activity-report-2017

[2] www.NIST.gov

In the event that the comment period is not extended, we also take this opportunity to share the following initial comments on the report.

U.S. public funding plays a key role in R&D for important medical products

As the largest funder of biomedical innovation in the world, the U.S. government plays a key role in researching and developing medicines, vaccines and diagnostics to address health needs. To date, through public funding contributed by American taxpayers, the U.S. government has contributed to the development of hundreds of medical products. A recent study found that funding from the NIH contributed to each of the 210 products approved between 2010 and 2016.[3] An earlier study found that when specifically considering a product's intellectual property, public-sector research institutes contributed to the development of 153 drugs, vaccines or new indications in under 20 years.[4] This funding has led to the development of lifesaving medical products used by MSF in our operations as well as other healthcare providers both in the U.S. and internationally.

However, MSF and people in America and around the world can only fully benefit from the important contributions from U.S. taxpayers if the resulting medical products are effective, safe, available, affordable and suitable for use in contexts where they are needed. MSF teams witness every day the consequences of people unable to access the medical tools they need. Existing U.S. law includes some assurance that action can be taken if federally funded inventions are not benefitting the public in key ways. These important protections should not be undermined, which several proposals within the green paper would do.

Regulations should not undermine the public's ability to benefit from publicly funded inventions

We are concerned by the proposed "intended actions" in Strategy 1 to narrow the scope of existing law that offer some safeguards to protect public access to publicly funded inventions through march-in rights. If enacted these changes would tip the balance away from an appropriate return on investment for public investments in R&D for medical technologies. Agencies relying on public funds to develop lifesaving medicines should not seek to curtail the public's right to appropriate, affordable access to the products developed with public support by this proposed unilateral regulatory action.

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[3] Clearly et al. Contribution of NIH funding to new drug approvals 2010–2016. PNAS (2018). Available from: https://www.pnas.org/content/115/10/2329

[4] Stevens et al. The Role of Public-Sector Research in the Discovery of Drugs and Vaccines. NEJM (2011). Available from: https://www.nejm.org/doi/10.1056/NEJMsa1008268?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

MSF objects to the "intended action" to "define the circumstances under which the government may exercise march-in rights" to exclude considerations of affordability. We urge the U.S. government not to "implement regulatory change under the Bayh-Dole Act to make explicit that the use of march-in rights specified in statute is reserved for a compelling national issue or declared national emergency when other remedies have failed." Having an overly narrow definition could tie the hands of federal agencies in the future to take action to ensure technologies are accessible for the public. Doing so goes against the stated goals of the administration to lower drug prices and call by more than 50 Members of Congress to use march-in rights to address "soaring" pharmaceutical prices.[5]

With regard to medical products, if the U.S. government does "require that the agency first conduct an informal consultation with the contractor, grantee, or licensee to understand the nature of the issue and consider other potential alternatives to remedy the concern [when considering exercising march-in right]," the agency should also be required to conduct a meaningful consultation with various affected stakeholders or those who make the request.

USG can support improvements to transparency and traceability of public funding

We note that strategy 4 includes some proposals that seek to improve public access to information on IP resulting from federal R&D programs. We hope that this will include timely information regarding proposals to license medical technology by the U.S. government.[6] It should also include clear and reliable data on the expenditures by the U.S. government that contributed to the development of the technology.

By promoting increased transparency of publicly funded and publicly developed biomedical R&D, the U.S. government can contribute to the dearth of reliable and transparent data on R&D expenditures and can improve understanding of the public's role in the biomedical innovation system.[7]

Evaluate public benefits by accessing new medicines they need

We note that strategy 5 includes proposals to evaluate the impact of federal funding on innovation. In order to measure the public benefits of these investments, such an evaluation should consider the extent to which the public is benefitting through access to any resulting medical products. Metrics could include the price of the product, any changes in price of the product, the number of countries where the product has been registered, estimated number of people who would benefit from the treatment who are receiving treatment.

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[5] https://www.keionline.org/22983

[6] See for example: https://www.keionline.org/29538; https://www.keionline.org/sites/default/files/KEI_MSF_NIH_Zika_Vaccine_License.pdf;

[7] https://www.doctorswithoutborders.org/sites/default/files/2018-06/us-based_groups_letter_to_hhs_on_increasing_transparency.pdf

Consider alternatives for improved public "returns" in the form of affordable and appropriate new technologies

The initiative considers "return on investment" (ROI) broadly in terms of benefits to society. However, premising the green paper on the notion that "reliable and predictable intellectual property rights are essential to incentivize innovation," overlooks the opportunity to also consider alternative incentives for innovation that may better deliver returns to the public in the form of accessible and affordable products to meet global health needs.

With suitably tailored incentive mechanisms the U.S. government could encourage innovators to deliver appropriate and affordable health technologies to patients in the US and beyond, instead of accepting high prices as inevitable and allowing R&D investments to be skewed towards the financial priorities induced by the patent system.

In addition to upholding safeguards intended to address failures of licensing agreements to protect access to publicly development medicines, the U.S. government could consider introducing more stringent conditions for public licensing and grants that ensure recipients to commit to timely and appropriate further development of a potential medical products, and widespread access to successfully developed products to ensure the greatest public return on these investments from the outset. MSF has offered more specific recommendations for such conditions in our submission to the U.S. Department of Health and Human Services' "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."[8]

Furthermore, examples of initiatives that have developed needed medical treatments and vaccines without relying on exclusivity as the method to incentivize innovation exist in several areas. The Meningitis Vaccine Project (MVP) in which the National Institutes of Health (NIH) played a crucial role is one such example.[9] The new all oral sleeping sickness treatment developed by the Drugs for Neglected Disease *initiative* (DNDi) and licensed by the European Medicines Agency (EMA) in 2018 is another.[10] Both of these examples show that a collaborative approach to product development which takes patient needs as the starting point can deliver affordable innovations at low cost.

Prize funds are another incentive mechanism to be explored. With a history that predates the patent system, prizes involve giving out payments on the achievement of pre-determined results. Prizes allow several promising research proposals to be pursued in parallel as they do not pick a winner early in the process. Prizes could serve as an alternative incentive to the granting of exclusive monopoly rights and should include contractual conditions to guarantee affordability through the surrender of exclusivity rights. This allows costs of medicines to get closer to the cost of production through competition where market size permits. Dozens of Members of Congress endorsed legislative proposals last year to introduce prize funds for biomedical innovation in the 115th Congress.[11]

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[8] https://doctorswithoutborders.org/sites/default/files/2018-07/HHS_Blueprint_Submission.pdf

[9] https://www.path.org/resources/meningitis-vaccine-project-website/

[10] https://www.dndi.org/2018/media-centre/press-releases/ema-recommends-fexinidazole-first-all-oral-treatment-sleeping-sickness/

Conclusion

For the past twenty years MSF has raised concerns with unaffordable medicine prices in contexts where we work, and in recent years this has been increasingly recognized as a global concern. Millions of people in America and around the world struggle to afford the medicines they need to live healthy and productive lives. In a time of skyrocketing medicine prices, we urge the U.S. government to not only uphold existing safeguards in U.S. law, but to also consider alternative incentives and initiatives to promote transparency, access and affordability for biomedical innovation to improve the public "return on innovation" to the benefit of all patients in need.

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[11] See for example, H.R. 1776 (2017) and S. 3411 (2018).

The Software Alliance BSA
Internet Association
SIIA

February 5, 2019

Walter G. Copan, Ph.D.
Under Secretary of Commerce for Standards and Technology
Director, National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Dear Under Secretary Copan,

Internet Association, BSA | The Software Alliance, and the Software and Information Industry Association are pleased to provide comments on the National Institute of Standards and Technology's ("NIST") draft green paper on the Return on Investment Initiative for Unleashing American Innovation ("Green Paper"). We share NIST's aim of maximizing innovation in our economy and appreciate your organization's efforts to achieve that goal.

Our associations represent the breadth of the tech industry, including software, internet, and cloud companies. Our goal is to foster innovation, promote economic growth, and empower people through the power of technology and the internet. Our member companies invest heavily in research and development and are committed to engaging in NIST's efforts to increase American innovation. We applaud NIST for including some very helpful recommendations, such as increasing the authority of agencies to protect the trade secrets of its private partners. Such a change would surely increase tech industry participation in public-private partnerships. We do, however, have concerns with the Green Paper's proposal to establish copyright for government-authored software.

The copyright laws emanate from the grant of power in Article I, Section 8, clause 8 of the Constitution, which permits Congress to confer exclusive rights to authors and inventors for limited times. The Founders included that provision to unleash innovation by creating a federally harmonized set of incentives for inventive and creative endeavors. Recognizing that such incentives are unnecessary for the production of government works,[1] federal law has since 1909 denied copyright protection for works authored by government employees within their employment. That principle was recodified in section 105 of the 1976 Act, which states that "Copyright protection under this title is not available for any work of the United States Government."

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[1] We note that as applied to private works, Congress has scrupulously maintained that incentive. For example, the Open Government Data Act creates a presumption that agencies

Section 105 reflects the commonsense proposition that copyright should not act as a barrier to the public's access to and use of materials created by the government. We are concerned by aspects of the Green Paper that could threaten such access. Specifically, the Green Paper recommends legal reforms, including amendments to Section 105, to "allow agencies to register a copyright to establish protection of the commercialization of 'software' that are products of R&D for which the Federal Government owns a right, title, or interest." In support of this recommendation, the Green Paper suggests that a lack of copyright protection has "led to lost opportunities to transfer software developed by Federal researchers," thereby creating a disincentive for commercialization. The Green Paper likewise asserts that the "ineligibility of the government to copyright software has frustrated endeavors to release and participate in open source development" because assets that are not subject to copyright protection cannot licensed on open source terms. Both claims merit closer examination.

The Green Paper's suggestion that a lack of copyright protection creates disincentives for commercialization of government-created software is predicated on a GAO Report from 1990. The GAO Report suggests "businesses are unwilling to invest in [government] software without copyright protection and some guarantee of exclusivity" and points to "[e]xecutives from two businesses" who "stated that [in order to invest in commercializing government-created code] their companies would require copyright protection and exclusivity to prevent competitors from marketing alternative software packages that are potentially less developed and less expensive." We are highly skeptical that the factual predicates of this nearly 30-year-old report remain accurate. Even putting that aside, we have significant concerns with the notion that the government could use copyright to afford any single entity with exclusive access to a government-authored work.

The Green Paper's suggestion that a lack of copyright protection for government works has thwarted open source development efforts is likewise deserving of further scrutiny. A variety of initiatives across the agencies signal an increasing interest in promoting more robust collaboration between the government and the open source community. To that end, in 2016, the Office of Management and Budget ("OMB") issued a Federal Source Code Policy with a three-year pilot project that requires government agencies to "release as [open source software] at least 20 percent" of any custom-developed code, including code developed entirely by government employees. To comply with this requirement, OMB directs agencies to "append appropriate OSS licenses to the source code."

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should make non-sensitive government data freely available to the public in open, machine-readable formats. The OGDA expressly preserves the existing incentives provided by intellectual property law for non-government works.

Although code wholly authored by government employees is not subject to copyright protection, agencies have developed a variety of approaches for complying with OMB's directive. The General Services Administration's digital services delivery team, 18F, has implemented the Federal Source Code Policy by making government-authored code available using a CC0 1.0 universal public domain dedication. NASA has developed its own open source license agreement that "relies on contract law wherever copyright law is unavailable as a means by which to enforce the agreement's terms and conditions." And in 2018, the Department of Defense developed an approach forged around a "Developer Certificate of Origin" process that is focused on obtaining a legal certification that the government author of code is intentionally making his or her contribution available under the license associated with the project.

We acknowledge that the various agency approaches for participating in open source development projects may reflect a degree of uncertainty about the ideal mechanism for contributing government-authored code to open source projects. However, conferring copyright protection to such code is a blunt solution that should be considered only as a last resort. Instead, we urge NIST to recommend that OMB convene relevant stakeholders for a survey of potential mechanisms by which agencies can comply with the Federal Source Code Policy by sharing government-authored code with the open source community under terms that are efficient, predictable and enforceable. Such a process should include licensing experts from the agencies that are subject to the Federal Source Code Policy, subject matter experts from the Copyright Office and Patent and Trademark Office, and representatives from industry, academia and the open source community.

We urge NIST to refrain from recommending the establishment of a copyright for software created by federal employees. Our associations appreciate the opportunity to comment on this draft Green Paper. While we wish to express our views on this specific recommendation, this does not diminish our broader support for NIST's efforts to enhance innovation and commercialization. The private sector is an essential partner in building on federal R&D, and intellectual property plays an important role in enabling this cycle of investment and innovation. We value the work NIST is doing to increase innovation in the economy and employ government investment for the benefit of the American people.

From: Chuck Neuenschwander - NA
To: roi
Cc: NIST Director
Subject: Comments: Draft Green Paper
Date: Wednesday, January 30, 2019 11:51:16 AM

Allow me to add my appreciation to that of others you must hear from for your efforts to tackle the issue of modernizing calcified rules and practices for dissemination of government sponsored innovation. I wish you the best of luck in moving the needle and I hope to help in some small way.

In my earlier submission ("an Inconvenient Problem") I touched on the lack of a cohesive strategy to deal with instances of unauthorized use of the fruits of innovation from government sponsored and paid-for research. Chastise me if I am wrong, but it appears little or nothing is said in the report on this subject. For instance:

- The words infringe or infringement can be found four times in the document
    - Page 26. "What We Heard: America Invents Act" – a generalization about the ability to receive an injunction.
    - Page 27. "Government Use License; Background" – a factoid about protections for the government's use of patented technology.
    - Page 39. "Software Copyright; Background" – a brief tutorial on copyright law as it relates to software.
- "Unauthorized" appears three times
    - Page 26. "What We Heard: America Invents Act" – again, injunction.
    - Page 92. "Federal IP Data Reporting System(s); Background – the need to properly secure proprietary information.
    - Page 104. "Strategy 5; Introduction" – balancing export laws and openness.

Here is a concern. I can accept that the issue I address can be outside the scope of this initiative. It is an inconvenient problem, but it is important for the stewards of government funded technology to deal with it. The proposal is not to immediately solve the problem, but to study it and propose policy if it is determined that the issue is large enough to warrant doing so.

To decide the value of pursuing this matter, please consider:

- How can there not be a policy – even if it is "turn a blind eye" – to guide all labs?
- If there is a problem, does anyone know how large it is?
- Is there no (muted?) clamor in the labs that, at least in the most egregious instances, there needs to be more enforcement?
- What is the incentive for someone in industry to enter into a paid-for tech-transfer license if they know they can get it free because they see others use government funded innovation without paying a royalty? What little royalty that exists might dry up. Further, notwithstanding the export control issue, outright infringement by foreign parties competing with industries in the U.S. is real and what is the policy and strategy for that?
    - If a policy is chosen that provides all transfers of technology to be royalty free, so a license is immaterial, does this apply to an international high-tech company in Asia?
- What is the impact on scientists and engineers seeing peers in industry whose patents

> are defended (and maybe the inventor rewarded) while their patents are infringed but no one cares? After all, Strategy 3 for the L2M CAP Goal is to "build a more entrepreneurial R&D workforce" and unsanctioned use of inventiveness throws cold water on putting in the effort to be entrepreneurial.

I know firsthand the reticence of many to address this matter; the push pull of dissemination vs protection. Because it is unknown whether there is a good answer, the tendency is to bury it, like the crazy uncle in the closet, and pretend it does not exist. That is wrong.

In conclusion, I believe: 1) the report needs a section that includes a discussion covering what is written here and 2) funding should be provided to create a study team to analyze the issue and make recommendations.

Good luck with your initiative.

My best regards,
Chuck Neuenschwander

Charles R. Neuenschwander
President

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January 9, 2019

Dr. Walter G. Copan
National Institute of Standards and Technology
U.S. Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

Dear Director Copan:

I write on behalf of Yale University to express my appreciation for the Administration's efforts to support and encourage the transfer of federally sponsored research into the commercial sector through its *Return on Investment Initiative for Unleashing American Innovation*. In particular, we applaud the recently released draft "Green Paper" (NIST Special Publication 1234), which we are pleased to note incorporates many of the comments and recommendations of research universities and technology transfer managers.

In general, Yale endorses the more extensive comments and recommendations submitted by the Association of American Universities (AAU), the Association of Public & Land-grand Universities (APLU), the Association of American Medical Colleges (AAMC), the Council on Government Relations (COGR), and the Association of University Technology Managers (AUTM) and specifically those relating to the critical importance of the Bayh-Dole Act to our technology transfer activities. In addition, we want to underscore our support for several Intended Actions in the Green Paper.

As discussed in Yale's response to the NIST RFI, we support the core concepts behind the conflict of interest regulations and policies, but the 2011 revisions have inhibited commercialization and imposed significant costs on universities, and have not materially improved objectivity in research. Harmonized, government-wide requirements for managing conflicts of interest, as proposed in the Green Paper, have the potential to better protect research integrity while promoting the commercialization of federally sponsored research. Also, as discussed previously, we support the Green Paper's Intended Action to clarify the interpretation and use of march-in rights under the Bayh Dole Act, which, if thoughtfully crafted, will ensure that early stage technologies will continue to be developed and made available to meet the needs of the American people while preserving the government's march-in rights in the event of a threat to public health or safety. Finally, we agree that there would be considerable benefit to the creation of a modern, unified platform for reporting data on intellectual property that is the result of federal research support, consistent with government-wide reporting obligations.

We greatly appreciate NIST's leadership in this multi-agency effort to improve technology transfer at universities and national laboratories. We look forward to future opportunities to comment as NIST and others implement their Intended Actions.

Sincerely,

Peter Schiffer

PUBLIC CITIZEN
1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

January 9, 2018

Dr. Walter Copan
Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 8930
Gaithersburg, MD 20899

Re: *NIST Special Publication 1234 - Unleashing American Innovation Draft Green Paper*

Dear Dr. Copan,

Public Citizen is a nonprofit consumer advocacy organization with over 400,000 members and supporters. We are writing today to urge the National Institute of Standards and Technology to reject technology transfer policies that would limit the government's existing authority to bring down the prices of federally-funded prescription drugs.

High drug prices are now epidemic. A January 2019 poll found that Americans consider taking action to lower prescription drug prices as the top priority for Congress.[1] Over the next decade, the Centers for Medicare & Medicaid Services project that retail drug spending will increase faster than any other major area of health care spending.[2]

On December 6th 2018, the National Institute of Standards and Technology (NIST) released a green paper proposing revisions to the rules governing the commercialization of technologies funded with federal tax dollars. The stated purpose of the paper is "to move the Nation to a new level of innovation performance that will increase the taxpayers return on their investment in federally funded R&D." But the proposed rules threaten to do just the opposite.

The federal government plays a major role in the research and development of new drugs. The green paper correctly notes that the U.S. innovation system is "substantially fueled by the discoveries and inventions arising from federally funded R&D at the Nation's universities, research institutes, and Federal Laboratories."[3] For example, one study found that the National Institutes of Health helped fund research associated with every one of the 210 new drugs approved by the Food and Drug Administration from 2010–2016.[4]

But since the enactment of the Bayh-Dole Act, the federal government has given away the fruits of the tens of billions of dollars of research it funds annually, granting corporations exclusive rights to commercialize government-funded inventions, with little commensurate benefit.[5] Bayh-Dole was introduced, under intense lobbying pressure, because valuable inventions were supposedly languishing in laboratories, and incentives were needed for commercialization. But this assumption was always questionable, and much evidence has emerged disputing the need to provide additional incentives.[6] The government has further sweetened the deal for corporations—and against the interests of taxpayers—by repeatedly failing to enforce its authority to demand reasonable pricing on federally-funded inventions.[7] As government giveaways have increased, so too have drug prices. The green paper ignores this context, and the plain text of the Act. Instead, it takes for granted the Act's success and proposes rules that entrench this imbalanced status quo further. The paper recommends explicitly eliminating pricing requirements and narrowing the government's rights in its own inventions.

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[1] POLITICO/Harvard T.H. Chan School of Public Health, Americans' Priorities for the New Congress in 2019, December 4 – 9, 2018, available at https://tinyurl.com/y8z5gbof.

[2] CMS, National Health Expenditure Projections 2017–26 (2018), available at https://tinyurl.com/ycwzmtfy.

[3] NIST, Unleashing American Innovation 5 (2017).

[4] Cleary E et al., "Contribution of NIH funding to new drug approvals 2010–2016," PNAS: Vol. 115: Iss. 10.

[5] This was not always the case. In 1947, for example, the Justice Department concluded that the rights to government-financed research and development inventions should always be assigned to the government. The Justice Department further

What the proposals will do, then, is to ensure that the taxpayers continue to pay twice for prescription drugs: first, for the knowledge base fundamental to their development, and then for the monopoly prices charged by manufacturers who piggyback on federal investment. These monopoly prices lead to treatment rationing. They leave legislators to make impossible choices between funding medicines and funding schools, leading to foreseeable and preventable suffering.[8] This is a poor return on investment. NIST should not confer additional monopoly protections to one of the world's most profitable industries.

Instead, NIST should strengthen the government's hand by delineating clear, actionable standards on when an invention is not "available to the public on reasonable terms" due to its price. NIST should also require public disclosure of all information necessary to determine whether licensees are serving the public interest.[9] Affordability must be recognized as a core benefit flowing from federally-funded research.

Sincerely,

Peter Maybarduk

Peter Maybarduk
Director, Global Access to Medicines Program
Public Citizen

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recommended that "as a basic policy all Government-owned inventions should be made fully, freely and unconditionally available to the public without charge, by public dedication or by royalty-free, non-exclusive licensing." Investigation of Government Patent Practices and Policies: A Report of the Attorney General to the President," 1947, quoted in Background Materials on Government Patent Policy: The Ownership of Inventions Resulting in Federally Funded Research and Development. Volume II: Reports of Committees, Commissions and Major Studies, House Committee on Science and Technology, August 1976 22.

[6] *See* A So et al., Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience, 6 PLoS Biology 10 (2008). ("Although universities can and do patent much more in the post-BD era than they did previously, neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively.")

[7] Robert Weissman, The Role of Federally-Funded University Research in the Patent System, Testimony Before the Committee on the Judiciary US Senate (2007), available at https://tinyurl.com/ya5x3nh7

[8] Drug Pricing Lab, Louisiana Budget Allocator, available at https://drugpricinglab.org/tools/louisiana-budget-allocator/

[9] Reporting requirements should include information about the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, pricing policies and key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights).

PhRMA
RESEARCH · PROGRESS · HOPE
950 F STREET, NW, SUITE 300 · WASHINGTON, DC 20004 · 202-835-3400 · PhRMA.org

January 9, 2019

National Institute of Standards and Technology (NIST)
U.S. Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

Re: NIST Return on Investment Initiative for Unleashing American Innovation: December 2018 Draft Green Paper

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide comments in response to NIST's December 2018 *Return on Investment Initiative for Unleashing American Innovation* Draft Green Paper (Green Paper).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.

PhRMA's comments focus on the first two components of NIST's Strategy 1, *Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices*, as presented in the Green Paper:[2]

(1) "Government Use License: Define the scope of the 'government use license'"; and
(2) "March-In Rights: Define the circumstances under which the government may exercise march-in rights to license further development of an invention to achieve practical application."

PhRMA is committed to ensuring the continued health and competitive strength of a biomedical research and development (R&D) ecosystem that fosters innovation, incentivizes competition, and benefits U.S. consumers. Moreover, strong and predictable intellectual property (IP) protections in the United States are essential to the United States' economic well-being, and signal to other jurisdictions the critically important economic benefits of IP. The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. The IP-intensive biopharmaceutical industry supports a total of more than 4.7 million jobs across the

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[1] NIST Return on Investment Initiative for Unleashing American Innovation Green Paper (Dec. 2018), https://www.nist.gov/sites/default/files/documents/2018/12/06/roi_initiative_draft_green_paper_nist_sp_1234.pdf [Hereinafter, "Green Paper"].
[2] *Id.* at 7.

U.S. economy and contributes $1.3 trillion in economic output when direct and indirect effects are considered.[3]

The Bayh-Dole Act helped establish a culture of entrepreneurship in America's universities and research institutes by creating a well-defined path to ownership and development rights for university researchers and spin-offs.[4,5] As a 2012 Congressional Research Service report found, "one of the major factors in the reported success of the Bayh-Dole Act is the *certainty it conveys concerning ownership of intellectual property*."[6] In addition, as the Director of the United States Patent and Trademark Office (USPTO) recently noted, "when patent owners and the public have confidence in the patent grant, inventors are encouraged to invent. Investments are made. Companies are created and grown. Jobs are created and science and technology advance."[7] Collectively, clear IP ownership by the grantee along with the certainty of exclusive licensing terms established under the Bayh-Dole Act have helped advance biomedical research by fostering the licensing of technology developed at least in part with federal funding for use by private sector entities. Such collaboration supports further significant innovation by private biopharmaceutical companies.

While we do not believe it is necessary to modify the regulations, NIST's proposal clearly and accurately articulates federal agencies' current interpretation of and approach to the "government use license" and "march-in rights" provisions of the Bayh-Dole Act. In doing so, NIST's efforts serve the important goals of that Act. We also offer additional suggested changes to NIST's proposals to provide greater clarity and certainty surrounding these issues.

NIST's Intended Action Would Be Consistent With the Current Scope of the "Government Use License" Under the Bayh-Dole Act.

Intended Action 1 of the Green Paper proposes changing the Bayh-Dole Act regulations to define the scope of the government's license "to practice or have practiced for or on behalf of the United States any Subject Invention," the so-called "government use license."[8] Neither of the two proposed changes alters the state of the law, but rather accurately re-articulates the already-operative definition of the government license in a clear way. This proposal would make explicit the current understanding of the license and provide clarity regarding the scope of the license in the context of the Bayh-Dole Act regime.

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[3] TEConomy Partners, The Economic Impact of the US Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; November 2017.

[4] President's Council of Advisors on Science and Technology (PCAST), Report to the President -- Transformation and Opportunity: The Future of the U.S. Research Enterprise (Nov. 2012), *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast_future_research_enterprise_20121130.pdf.

[5] D'Este P, Perkmann M. Why do academics engage with industry? The entrepreneurial university and individual motivations. J Technol. Transf. 2011;36(3):316–39.

[6] Schacht, W. The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Congressional Research Service Report 7-5700 (Dec. 3, 2012)(emphasis added), *available at* https://www.fas.org/sgp/crs/misc/RL32076.pdf.

[7] Andrei Iancu, Director of U.S. Patent and Trademark Office, comments at NIST symposium presentation (Apr. 19, 2018), *available at* https://www.nist.gov/tpo/return-investment-roi-initiative/unleashing-american-innovation-symposium.

[8] *See* Green Paper at 28; *see also* 35 U.S.C. § 202(c)(4); 37 C.F.R. § 401.14(b).

The proposed changes are as follows:[9]

- Insert a new definition in 37 CFR 401.2: "The term ***government use*** is defined as use directly by the government for a government purpose and the direct benefit of an agency, not to the benefit of a third party even if related to the government mission. Continued use in research and development by the government is included."
- Insert new language into the existing standard patent rights clause in 37 CFR 401.14(b) "Allocation of Principal Rights" clause: "The government use license is restricted by the following conditions: (A) for use directly by the government or on behalf of the government for its own consumption or practice for its own direct benefit. (B) to continue to perform research. (C) This right does not extend authority to third parties to make, sell, or otherwise distribute goods and services as a commercial product where the government is not procuring the goods or services for its own direct use or consumption through a contract."

Of particular importance, under NIST's proposal, the term "government use license" means "use directly by the government—or a government contractor in performance of an agreement with the government—for a government purpose only, including continued use in research and development by the government."[10] NIST rightly observes that the license "should not extend to goods and services made, sold, or otherwise distributed by third parties if the government—or a government contractor in the performance of an agreement with the government—does not directly use or consume those goods and services."[11] NIST's proposals reflect existing interpretations of this term, by making clear that the license only extends to third-party goods or services *directly* used or consumed by the government.[12]

NIST's proposals capture and define Federal agencies' two-decade old understanding of and approach to the government use license, and this change will benefit all stakeholders seeking greater clarity and certainty in the scope of the government use license. For example, a report by the Government Accountability Office (GAO) describes the government use license as giving the government the right to use a subject invention in two situations: (1) when contracting with a third party to make a product that incorporates the invention for or on behalf of the government, provided use of the government's license satisfies a legitimate federal governmental need in support of a congressionally authorized program; or (2) when the government or a recipient of federal financial assistance uses the invention in further government-funded research, provided that such research serves a legitimate government need for the agency exercising the license.[13] This understanding by GAO is consistent with the long-standing approach of the government use license from the Department of Defense and the National Institutes of Health (NIH), which refer to it as a license "for government purposes."[14]

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[9] Green Paper at 29, n. 43.

[10] *Id.* at 28.

[11] *Id.*

[12] *Cf. Innovative Concepts, Inc. v. Symetrics Indus., Inc.*, No. 02-1040-A (E.D. Va. 2003) (direct sale to a foreign government by a third party that had obtained computer software with government purpose rights was not a "government purpose"); *Aktiebolaget Bofors v. United States*, 139 Ct. Cl. 642 (1957) (license to use drawings "for United States use" barred use to manufacture guns for supply to other countries).

[13] *See* General Accounting Office, *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions*, 5–6 (July 2003), *available at* http://www.gao.gov/assets/240/238890.pdf.

We appreciate NIST's clear restatement of the current and long-standing operative definition of the government use license, and its efforts to provide greater certainty and clarity to stakeholders in understanding the provisions of the Bayh-Dole Act. NIST's proposals would provide greater certainty and clarity to the scope of the government use license.[15]

NIST's Intended Action Would Reflect Current Appropriate Interpretations of the "March-in Rights" Provisions of the Bayh-Dole Act.

NIST's proposals regarding march-in rights would codify the existing approach of Federal agencies to march-in rights, and we support NIST's efforts to provide greater clarity and certainty regarding the current state of the law.

NIST's Intended Action 2 proposes changing the Bayh-Dole Act regulations to (a) make explicit that the actionable bases for exercising march-in rights in 35 U.S.C. § 203(a) would be reserved for uses that address a compelling national issue or a declared national emergency when other remedies have failed; (b) specify that march-in rights should not be used as a mechanism to control or regulate the market price of goods and services; (c) provide a clear and consistent definition for "reasonable terms" contained within the existing statutory definition of "practical application," including clarifying that the intent of reasonable licensing terms is to allow a product or service to reach the marketplace but not as terms for consumer use (i.e., price control mechanism); and (d) require that an agency first conduct an informal consultation with the contractor, grantee, or licensee when it receives information that it believes might warrant march-in to understand the nature of the issue and consider other potential alternatives.[16]

Each of the changes proposed by NIST accords with the understanding of the original sponsors of the Bayh-Dole Act, whose "intent was to ensure that products were licensed for reasonable terms rather than being used as a price control."[17] Further, the proposed changes align with the current, long-standing state of the law. As NIST indicates, in all six publicly reported cases where NIH received formal petitions to initiate march-in proceedings, it has determined that the criteria for exercising march-in rights were not met.[18]

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[14] *See* Dep't of Defense, *Intellectual Property: Navigating Through Commercial Waters, Department of Defense*, 2–3, *available at* http://www.acq.osd.mil/dpap/Docs/intelprop.pdf (stating that "the Government receives a nonexclusive license to use [the subject] invention for Government purposes."); Nat'l Institute of Health, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interest are Protected*, 5 (July 2001), *available at* http://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf ("By law, the funding agency retains residual interest in grant- and contracts-supported inventions, such as a royalty-free, paid-up license to use the technology for government purposes."); *see also* DFARS 252.227-7013(a)(12) (explicitly excluding use of a government purpose license in data for commercial purposes); DFARS 252.227-7014(a)(11) (same); DFARS 252.227-7018(a)(14) (same).

[15] In line with NIST's proposed regulatory changes, it also would be worth noting in any regulatory amendment that the government use license must be in furtherance of a legitimate agency need authorized by Congress, as discussed in the GAO report.

[16] Green Paper at 33–34.

[17] *Id.* at 31. *See also* Statements by Senators Bayh and Dole, "Our Law Helps Patients Get New Drugs Sooner," Washington Post, April 11, 2002.

NIST's articulation of the government's current approach for exercising march-in rights would provide clarity and certainty to stakeholders. NIST's approach also addresses important concerns stakeholders voiced in response to its RFI, including that using march-in rights as a price control would "impede[] the creation of new drugs and discourage[] university and medical school licensees from making the substantial additional investments necessary to develop and commercialize new drug discoveries," as well as create "uncertainties in the U.S. innovation system" and lead to "lack of confidence that patents will be enforceable in fair court proceedings or in the U.S. Patent and Trademark Office's Patent Trial and Appeal Board."[19] Importantly, NIST notes that some of its RFI respondents "report that the threat of march-in has prevented licensing deals that would have otherwise occurred, leading to technologies languishing in contravention to the law's stated purpose."[20] Our hope is that with greater certainty brought by NIST's proposals, licensing deals in the future will no longer fail to materialize due to uncertainty in the scope of march-in rights.

Additionally, we commend NIST's proposed requirement that Federal agencies coordinate with organizations (i.e., contractors) holding title to Subject Inventions or exclusive licensees of those inventions upon receiving a march-in request. NIST's proposed change could provide useful industry perspective, increase communication between private industry title-holders or licensees and funding agencies, and reduce the government's burden of responding to third-party march-in requests. We suggest that in addition to consulting title holders, Federal agencies should also seek consultation with any exclusive licensees. In many instances, exclusive licensees possess important information demonstrating efforts to commercialize a Subject Invention or the successes achieved in a commercial product incorporating a Subject Invention. However, to date, Federal agencies have expressed hesitancy to engage exclusive licensees concerning Bayh-Dole Act matters. We would also suggest adding clarifying language to any relevant regulatory change to make clear that the informal discussions are for the agency and Subject Invention title holder and/or exclusive licensee only, and not the organization submitting a march-in petition, as such organizations have the opportunity to provide supporting information when submitting a march-in petition.

We applaud NIST's clear and correct articulation of the limited circumstances under which the government may exercise march-in rights. While not necessary, to the extent NIST seeks to introduce regulatory amendments to clarify the march-in rights provisions, PhRMA respectfully asks that NIST make changes consistent with what is proposed in the Green Paper.

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[18] Determination in the Case of Petition of CellPro, Inc. (1997); Determination in the Case of Norvir (2004); Determination in the case of Xalatan (2004); Determination in the Case of Fabrazyme (2010); Determination in the Case of Norvir II (2013); Determination in the Case of Xtandi (2016).

[19] Green Paper at 31–33.

[20] *Id.* at 32.

Conclusion

PhRMA appreciates the opportunity to comment on the proposals NIST provides in the Green Paper. We particularly welcome NIST's efforts to make clear the existing requirements of the Bayh-Dole Act concerning government use licenses and march-in rights. In the research-based biopharmaceutical industry, clearly-defined IP rights are critical to fostering innovation, ensuring continued R&D, and facilitating the successful transfer of technology. To that end, NIST's proposed changes can play an important role by providing further clarity to stakeholders who rely on the protections that the Bayh-Dole Act provides to government-funded IP.

Sincerely,

/s/	/s/
Anne McDonald Pritchett, PhD	David E. Korn
Senior Vice President, Policy and Research	Vice President, Intellectual Property and Law

Dr. Courtney Silverthorn
Deputy Director, Technology Partnerships Office
National Institutes of Standards and Technology
100 Bureau Drive MS 2201
Gaithersburg, MD 20899

February 5 Comments on the Return on Investment Initiative Green Paper

Dear Dr. Silverthorn,

I submit this letter as a replacement of my January 9th letter, as at that time, I had not yet read the NIST GCR 18-017 report "The Economic Impacts of the Advanced Encryption Standard".

Thank you for the impressive and thoughtful work that went into producing the Green Paper, and the opportunity to provide feedback on it. The document itself sheds light on federal technology transfer practices and policies and as such is inherently valuable.

I agree with the comments provided by AUTM and offer some additional comments labeled to correspond to the Intended Action "IA" reference.

In addition, I believe that there are leadership opportunities for NIST in facilitating the use of secure data (IA8 and IA9), and in advancing our methods for valuing cost saving technical advances (IA15).

POTENTIAL LEADERSHIP OPPORTUNITIES FOR NIST IN DATA POOLING

Digital security:

Kudos to NIST for the role they have played https://www.nist.gov/publications/economic-impacts-advanced-encryption-standard-1996-2017 and continue to play https://www.nist.gov/news-events/news/2019/01/nist-reveals-26-algorithms-advancing-post-quantum-crypto-semifinals in encryption and data sharing standards.

Value creation by facilitating the application of deep learning to training sets:

In my experience, value creation is being delayed by a lack of experience on how to share and license data and training sets, in part because of valid privacy and confidentiality concerns, and in part because of reasonable uncertainty about "fair" use and "fared" use. The most relevant article on this topic I found so far is about artistic works ***"Artificial Intelligence's Fair Use Crisis"*** https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3032076

This topic was discussed at the recent Boston LES meeting, and both practical as well as ethical issues came up. One panelist remarked that they were waiting for an "evolving consensus" on how to share, even temporarily (as is the case for use as a training set) certain data. The NIH played a key role in developing a consensus regarding materials transfers. I urge NIST to take a leadership role in developing a consensus regarding the secure, fair and "fared" uses of pooled data.

IA3C and IA3D, on expanding the need to apply for a waiver to foreign nonexclusive licenses:
These intended actions items are counterproductive, interfering with Goals 2 and 3 in particular, and will lead to an overall reduction in our returns on federal research investments.

Licenses with and without exclusivity serve very different roles in the innovation ecosystem.

As noted in the AUTM comments, nonexclusive licensing is often done when products are close to launch, or after they were introduced into the marketplace. Not surprisingly, nonexclusive licenses tend to be executed longer after the patents are issued or filed. The technologies literally are, as a group, more mature, and for whatever reason were not licensed closer to the time of initial conception and reduction to practice. In contrast, licenses with some exclusivity in them (exclusivity can be nuanced by technical field, market, geographical location, or any other term the parties define) act more as commercial development incentives, attracting private sector dollars.

Consequently, it is reasonable to incentivize domestic manufacture via prudent and thoughtful granting of licenses with exclusivity, as the licenses themselves are commercial development incentives for not yet developed technology. Since nonexclusive licenses for the most part are not development incentives, placing too many hoops between a potential paying nonexclusive licensee, who may already be commercializing or close to commercializing the product, may have no to little effect on the location of manufacture of the product, while depriving the technology owner of some revenue, the inventor of the satisfaction of knowing that their invention is commercially relevant, and potentially, in due course, an ability to build a more engaged, and domestically based relationship with the nonexclusive licensee.

IA3A and IA3B, on streamlining the waiver process:
Licenses with exclusivity in them tend to have enforceable diligence in them, - so called use it or lose it provisions. Nonexclusive licenses seldom do, and if they are present, are considerably weaker. Because of the diligence provisions, public availability may, under certain circumstances, be better served by a committed foreign licensee than by no licensee, or by an uncommitted domestic one. Thus, providing an opportunity to request a waiver to the domestic manufacture requirement for licenses with exclusivity in them is a reasonable and useful aspect of the technology transfer system.

IA4 and IA5:
Kudos to NIST for recognizing the growing importance of software, data and trade secrets to the U.S. economy, and for supporting expanding copyright protection available for federal laboratory software, and for taking steps to more uniformly and predictably secure and manage private sector trade secrets which may be shared with federal laboratories.

IA9, expression of concern:
I am not an expert on the reasons for there being such a large variety of technology transfer contract types, or the need for an even larger variety. However, a large and growing proliferation of contract types, (Appendices 1 and 2 of the Green Paper), adds to the confusion of potential

partners, and complicates Goal 5.

As a taxpayer, some of the terms in Appendix 2 are concerning, particularly if federal laboratories are being asked to produce commercial deliverables for funders.

Explain the need, if there is one, for additional contract types before further complicating the current situation, lest we never understand it enough to streamline, improve, or benchmark it.

IA13, 14, and 15, general:
We want and need a mix of customized measures by and for our community, and measures which are recognized as standard economic measures for national and international communication.

Approaches to valuing cost saving or cost avoidance technologies are less well developed than those designed to assess value creation. NIST may be uniquely positioned to take a leadership role in this area.

One of AUTM's strengths has been the engagement of its members. Updates to tools must include significant and ongoing input from the users the tools, including explicitly, federal laboratory technology transfer practitioners and AUTM member technology transfer practitioners. Updates to measures must include input from both the providers and the users of the data elements.

In due course, we, as a nation, should be aiming for a single system which evolves slowly, and which, in addition to tracking research inputs also tracks downstream results The current list of things to count and observe; research expenditures, invention disclosures, intellectual property protection, license contracts, companies formed to commercialize technology, products or services introduced which use the licensed technology, and earned royalties is useful if incomplete. The existence of a single system does not preclude other approaches, -just that there should be a set of standard measures lest we leave ourselves with no basis of comparison.

Timelines, -how long things take, are a highly underutilized performance metric. They are objective and readily available. The issue has simply been indexing, or associating sequences of dates to form a commercialization narrative.

In due course, we should involve the Science and Engineering Indicator team and resources.

In due course, we should be aware of innovation metrics developed by the OECD and consider incorporating them. One interesting example is triadic patent families, patent families where there is a US, European, and Japanese family member. https://data.oecd.org/rd/triadic-patent-families.htm While these foreign patents may be an indication of foreign manufacturing, or sales, or use, or importation, they do provide revenue back to a U.S. entity, and are very interesting and useful indicators of trends.

Additional IA 13 recommendation:
I support the requirement to state the appropriate alphanumeric indicators of funding contracts on the face of patents so they are easily searchable and findable.

Additional IA 13 recommendation:
I support a single name for federal reporting entities. One of the challenges of simply finding and counting patents of universities and federal agencies is the profusion of names used by the same entity, due primarily to significant variation in abbreviations used.

IA14, A and B:
I express mild support creating such a portal, or potentially joining forces with AUTM and using AUTM's portal, particularly if the portal adds to inventor engagement. However, simply posting technologies, especially nonconfidentially, as they must be, in my experience is not particularly useful.

Inventors often have the best insight into potential commercialization partners, and so called rifle shot marketing is more effective than broad brush marketing. That said, anything which encourages interaction between the inventors and potential partners from the commercial sector is good, and often simply preparing the description for the posting engages the inventors in a way they may not have been engaged previously.

To the extent that the portal fosters engagement and involvement it is a plus. If instead it is seen as a compliance chore, it will accomplish little and decrease efficiency and time spent actually commercializing the technologies.

Personal interactions, such as those contemplated by IA11, are in my view, more important.

IA15:
Additional IA15 comments:
Models and data evolve in concert, providing that consistent definitions are maintained, and only changed after a great deal of thought and discussion, and then well documented. AUTM has conducted a survey, with integral Instructions & Definitions, by and for its members for more than two decades.

From what I have been able to observe, the federal laboratories do not have an analogous effort, and this has frustrated efforts to gather meaningful data about federal laboratory technology transfer.

The federal technology transfer practitioners must have a say in the data elements they report and they must use consistent definitions. If this cannot happen, then all involved are wasting their valuable time.

From what I have been able to infer from Appendix 2 of the Green Paper, it appears that a significant form of federal laboratory technology transfer is privately funded contract research at the federal laboratories, -what a university would call sponsored research. Research associated with license agreements (for example, a requirement to fund work at the university could be one of the forms of diligence) used to be a data element in the AUTM survey. In part, because many technology transfer offices did not track the actual amount of sponsored research in their databases, this was dropped from the AUTM survey, though offices often chose to report it in their annual reports as a sign of commercial engagement and overall contribution to the university research base.

Additional IA 15 recommendation:
At least on a trial basis, include total private sector contract research expenditures in federal laboratory metrics. If the contract itself is reported, whether as a CRDA, SPP, ACT, or other contract, type, and funds are paid from the for profit partner to the federal laboratory, this fact and the aggregate sum should be reported and acknowledged as an important indicator of commercial engagement (provided of course that confidentiality can be properly maintained).

Consider using Pajek diagrams to illustrate growing public private commercialization networks.

Consider using Pajek diagrams to illustrate the growing network of users and beneficiaries of NIST's cryptographic validation program. Providing confidentiality can be maintained, show the number of new and repeat users, potentially characterized by size, type or sector Such an illustration could show the growth of secure data transmission and storage in the United States.

Thank you for your thoughtful consideration of these comments and for the vitally important work NIST does on our behalf.

Respectfully,
Lori Pressman
Lori Pressman

LSAB
MARYLAND
LIFE SCIENCES ADVISORY BOARD

January 2, 2019

Dr. Walter G. Copan

Under Secretary of Commerce for Standards and Technology
and Director of NIST
Gaithersburg, Maryland 20899

Dear Dr. Copan:

On behalf of the Maryland Life Sciences Advisory Board Federal Laboratory Commercialization Task Force, we would like to thank you and your team at NIST for producing the NIST 'Green Paper' *Return on Investment Initiative for Unleashing American Innovation*.

The Task Force previously submitted testimony and extensive comments to NIST, and we are pleased to see many of these comments reflected in the Green Paper, and we would like to take this opportunity to re-emphasize several points that are highlighted in the paper:

Federal Researcher Entrepreneurial Workforce:

Reforming conflict of interest rules are critically important for civil service researchers working in government owned and operated laboratories, such as NIH. Creating new conflict of interest rules for federal researchers, similar to those employed at research universities, is vital where conflicts are managed by disinterested parties supervising the research units, with frequent and transparent reporting and approval guidelines. Current federal conflict of interest statutes do not easily accommodate the role of a federal researcher working on an entrepreneurial project, which is allowed by other federal statutes. This may require federal statutory reform, as has been the experience for public research universities at the state level in the U.S

Additionally, to ensure that federal research jobs remain attractive to younger researchers, ensuring these entrepreneurially minded researchers have defined pathways to experiment with assignments or entrepreneurial leave is necessary. Use of Intergovernmental Personnel Act (IPA) assignments where a federal researcher might be appointed to a research university to work on a commercial project is one vehicle. The Department of Energy has an entrepreneurial leave policy for researchers at Sandia Labs where researchers are allowed up to three years leave time to work on entrepreneurial projects, with a guarantee that the position will be open during the time period.

Federal Lab Private Sector Engagement:

Given the number of government owned-government operated federal laboratories in the Greater Washington region, it is critical to ensure that additional flexibility be granted. These might include expanded Other Transactions

Authority (OTA) and expanded Enhanced Use Lease Authority (ELA) and other authorities that are currently limited to specific federal agencies, but might be given broader application across all agencies to unleash more innovation.

We are pleased that use of Congressionally chartered foundations are called out as one possible vehicle to provide needed regulatory flexibility, and our Task Force stands ready to provide assistance and advice.

Flexibility in Use of Federal R and D Funds by Federal Recipients

We continue to be interested in new approaches to recipients of federal funding such as ability of researchers to employ federal funds towards patent costs and other reforms, including removing restrictions on intellectual property negotiations where corporate funded research is performed in facilities funded with tax-exempt bonds at universities.

Thank you for the opportunity to provide further feedback. As mentioned earlier, the Task Force is ready to work on refinement of these policies and ideas with the NIST Team and other groups interested in this important topic.

Sincerely yours,

The Maryland Governor’s Life Science Advisory Board

Jay Perman, Chairman
President, University of Maryland, Baltimore

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Tom Ridge
Chairman, Board of Trustees

January 9, 2019

Walter G. Copan, Ph.D.
Under Secretary of Commerce for Standards and Technology
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Dear Under Secretary Copan:

On behalf of numerous state, local, university and nonprofit organizations around the country, SSTI thanks you for your leadership on the Return on Investment (ROI) Initiative for Unleashing American Innovation and welcomes the opportunity to comment on the draft green paper (NIST special publication 1234).

America makes a significant annual investment in the future through a commitment to R&D, and the National Institute of Standards and Technology (NIST)—as well as the White House Office of Management and Budget—are right to recognize that the country can do better than to leave the outcomes of this research to chance. The ROI Initiative is an important step toward a federal commitment to improving the efficiency and efficacy of these outcomes.

SSTI, a nonprofit organization founded in 1996, strengthens initiatives to create a better future through science, technology, innovation and entrepreneurship. The members that comprise our network work with researchers and entrepreneurs to transform American innovations into new solutions, products and jobs. These organizations provide technical assistance, business development services, investment capital and other support to scale innovations.

The ROI Initiative provides an opportunity to further leverage the experience of these organizations to achieve greater returns on the nation's investments in R&D. Our comments on the draft green paper focus on the areas that are most directly related to federal-regional-industry collaboration.

NIST has identified a number of promising initiatives to expand in order to unlock greater ROI. Recommendations of particular note to regional innovation economies include the following:

- Expanding the use of the Agreement for Commercializing Technology (ACT) contracting mechanism, is the right direction for federal labs. The U.S. Department of Energy[*] and anecdotal evidence suggests that these agreements may effectively provide greater flexibility for federal-industry partnerships.

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[*] U.S. Department of Energy. (2017). *Annual Report on the State of the DOE National Laboratories*. Retrieved from: https://www.energy.gov/sites/prod/files/2017/02/f34/DOE%20State%20of%20the%20National%20Labs%20Report%2002132017.pdf.

- Providing a clear and universal entrepreneurial leave policy for federal scientists and engineers is a sensible strategy to, in the best case scenario, help scale innovative businesses and would also provide employees with invaluable entrepreneurial experience.

- Committing to further measurement of technology transfer and commercial outcomes is also critical for federal partners and taxpayers, so that strategies can be properly evaluated and adjusted or abandoned.

One initiative discussed in the draft green paper of particular importance to regional technology-based economic development organizations is SBIR/STTR. We recognize, as explained in the paper, that most SBIR policy suggestions are more appropriately directed to the U.S. Small Business Administration (SBA). However, considering the attention given to the program in the draft green paper, we want to reiterate the importance—and potential for continued improvement—of SBIR/STTR for increasing America's ROI on innovation. With last year's defense authorization, Congress temporarily approved useful changes to the program. These include allowing agencies to continue using a portion of their funds to support program outreach, "Phase 0" programs and other services related to improving the overall function of SBIR. The legislation also allows a portion of grant funds to be used for business development services, which should help recipients receive critical assistance for the market-focused aspects of their enterprise. With these changes, SBIR/STTR can be better-aligned with proven venture development practices, which emphasize business development in tandem with technology development. We strongly encourage NIST, SBA, and other federal agencies to emphasize the further integration of SBIR/STTR with existing services and organizations that support high-growth venture development.

We also appreciate NIST's recognition of continued support for technology entrepreneurship programs, and we echo the paper's attention to the wide variety of available initiatives. I-Corps has fairly been recognized as an interesting tool for helping to change the mindset of investigators, but the program's "lean"-focused curriculum is at the root of *many* venture- and entrepreneur-development programs throughout the country. Depending on whether staff training—and hands-on experience—in entrepreneurship is a primary or secondary goal, accelerators, incubators, entrepreneur-in-residence, entrepreneurial leave, and classroom training models are offered by numerous venture development organizations, universities and other partners throughout the country. NIST's program-neutral recommendation to "establish technology entrepreneurship programs at Federal R&D agencies government-wide" is exactly right.

One omission from the draft green paper is a call for a uniform federal initiative to support regional initiatives to transform federal R&D into solutions for the American people. This type of investment would greatly improve the nation's ROI, yet is lacking in current federal policy. SBIR/STTR provides funding directly to businesses, and each agency has partner and service expectations. I-Corps is not primarily a venture-focused program (with six exits for 583 startups noted in the paper) and is operated agency-by-participating agency.

The U.S. Department of Commerce's Regional Innovation Strategies (RIS) program can provide funding for regions that identify the transformation of federal intramural R&D as a local need but is insufficient at $21 million in the most recent budget. Whether by dramatically increasing the scale of the RIS program or by creating a new program, such as that proposed in the bipartisan *Startup Act* by Senators Jerry Moran, Mark Warner, Roy Blunt and Amy Klobuchar, the country should be making stronger investments in organizations that can work with researchers, entrepreneurs, established corporations and other partners to better unleash American innovation.

Once again, we appreciate NIST's attention to the ROI Initiative for Unleashing American Innovation, and the thoughtful development of this draft green paper. Better policies and greater investment in technology transfer and commercialization can yield a greater return on our R&D investment. SSTI and our members stand ready to work with you and NIST throughout this process.

Sincerely,

Dan Berglund

Dan Berglund
President and CEO
SSTI

STM 50
The global voice of scholarly publishing

09 January 2019

Dr. Walter G. Copan
Director, National Institute of Standards and Technology
100 Bureau Dr., Stop 1070
Gaithersburg, MD 20899-1070

Re: STM feedback on NIST Special Publication 1234

Dear Dr. Copan:

On behalf of the International Association of Scientific, Technical and Medical Publishers (STM), I want to thank you for the opportunity to comment on NIST Special Publication 1234, "Return on Investment Initiative for Unleashing American Innovation." The members of STM stand in strong support of the Administration's efforts to maximize the value of the transfer of Federal investments in science and technology. In fact, in fulfilling their commitment to communicate the latest discoveries, our members already work with all funders and practitioners of research towards enabling innovation and further discovery. Publishers diligently work to ensure that discoveries are able to be understood, trusted, and built upon, and look forward to continuing our collaborative work with the Administration to implement our shared goals.

STM is the leading global trade association for academic and professional publishers. It has more than 150 members in 21 countries who each year collectively publish more than 66% of all journal articles, as well as tens of thousands of monographs and reference works. STM members include non-profit scientific and scholarly societies, commercial publishers, and university presses who work collectively to ensure broad access to and use of the latest scientific and scholarly information. The majority of our members are small businesses and not-for-profit organizations, who represent tens of thousands of publishing employees, editors and authors, and other professionals across the United States and world who regularly contribute to the advancement of science, learning, culture and innovation throughout the nation. They comprise the bulk of a $25 billion publishing industry that contributes significantly to the U.S. economy and enhances the U.S. balance of trade.

We want to reiterate our support for the initiative, and our appreciation of the opportunities that were provided during the process of the green paper's development for feedback. Our comments in this letter echo those we submitted in response to the "Request for Information Regarding Federal Technology Transfer Authorities and Processes," as published on May 1, 2018 in 83 FR 19052, Docket Number: 180220199-819-01, but build on those comments in the context of the current green paper. We would also welcome an opportunity for face-to-face discussion about the many ways that data can be leveraged to increase the government's ROI, and could make our experts available for a discussion at your convenience to help with finalizing the draft green paper.

In advance of any direct dialogue, we would like to emphasize our appreciation for the green paper's recognition of the importance of intellectual property. As noted in the paper, innovations, knowledge, and creations are appropriately protected through intellectual property (IP), and significant strategic value can be created by managing these IP rights. Critically, the creation and dissemination of new products and opportunities is enabled through non-federal ownership of IP, which delivers significant ROI to the public. The report recognizes that IP in this case is not limited to patents, but also includes copyright, trademarks, and trade secrets, which are each important forms of IP that are being used to ensure the broadest possible impact of federal research.

To encourage more entrepreneurial activity and a greater ROI, the report helpfully suggests that the government should clarify, through consistent and streamlined government-wide policies and practices, the ownership, use, and compulsory licensing of IP. In particular, we strongly support the intention expressed in the document that the application of "government use licenses" be limited and that any use be construed narrowly. In particular, we appreciate "Intended Action 1" and the regulatory changes suggested in footnote 43. Additional language would be helpful to indicate that the government use license should be limited to internal use by the government. We also recommend that the language of the regulatory change suggested in the second bullet of footnote 43 be expanded to apply to all forms of IP related to Federal and Federally-funded research. These clarifications would greatly increase the potential for commercialization by removing uncertainty about competing government use.

We also agree that, as noted throughout the document, additional steps must be taken to ensure the greatest possible return on investment for federal research and development, and that researchers and innovators can commercialize digital products reporting on or deriving from federal R&D. Intended Action 8, to establish consistency government-wide, would be an excellent step in this direction.

We noted in our earlier submission that the US Department of Education's Open Licensing Requirement for Competitive Grant Programs runs counter to the expressed goals of the ROI initiative and the Lab-to-Market cross agency priority (CAP) goal of the President's Management Agenda (PMA), as well as the central principle of the Bayh-Dole Act. As NIST moves ahead with its partners to implement Intended Action 8, it will be important to address such policies that actively prevent the commercialization of intellectual property created by a grant recipient, moving them into harmonization with other government policies and the cross-agency priority.

Additional consideration is required for the new federal policies regarding data, including data arising from federal R&D. While this topic is the subject of considerable discussion within the Administration, including through the Federal Data Strategy, it would be appropriate to also consider the topic in the context of the ROI initiative. Specifically, federal policies that aim to make data more available to the public in order to increase the ROI for the taxpayer must be coordinated across agencies and must also ensure that any IP rights related to data – including copyrights, patents and trade secrets – are respected. Data is the next frontier, and the government should avoid creating the barriers to translation, commercialization, and collaboration that exist with respect to other R&D assets. The recommendations and results of the green paper could be productively applied to this area moving forward. Publishers have spent a great deal of time over the past decade carefully considering opportunities for creating value with data and we would welcome the opportunity to discuss the issues involved further.

Thank you for your work on this initiative, and your continuing engagement with the stakeholder community. Please let us know if you would be willing to discuss these issues in a face-to-face meeting in the coming months. We look forward to continuing to assist agencies maximise the potential of Federal investments in science and technology.

Very truly yours,

Michael Mabe
CEO STM

From: Swearingen, Will
To: roi
Cc: Cusker, Brett; Friesenhahn, Ray; Swearingen, Will; Dave Appler; Jagadeesh Pamulapati
Subject: Input for "Green Paper" on Return on Investment Initiative for Unleashing American Innovation
Date: Monday, December 10, 2018 6:35:00 PM

NIST Green Paper Authors,

I have read with interest your draft Green Paper, *Return on Investment Initiative for Unleashing American Innovation.* I applaud this initiative. I am writing to provide short but important inputs to the draft paper.

Economic-Impact Studies: The paper mentions how economic-impact studies can serve as an important tool to measure the ROI of technology transfer. The paper on p. 108 mentions an AUTM study to estimate the economic impact of academic licensing and a similar experiment to use this approach by NIST for federal laboratory licensing. In addition, on pp. 109-110, it mentions that economic-impact studies can be useful for assessing the ROI of institutions. However, the paper does not mention two major comprehensive Department of Defense-funded studies of the economic impact of DoD license agreements with industry. These studies are distinguished from the studies you mention because, rather than estimating sales from royalties, they involved actually contacting the licensees and asking about the sales of new products and services based on the licensed technology (achieving a response rate of over 90%). These studies are:

1. *National Economic Impacts from DoD License Agreements with U.S. Industry, 2000-2014* (January 2016) https://techlinkcenter.org/wp-content/uploads/2017/01/2016-DoD-Licensing-Study-E-Publication.pdf
2. *National Economic Impacts from DoD License Agreements with U.S. Industry, 2000-2011* (January 2013) https://techlinkcenter.org/wp-content/uploads/2017/05/DoD-Economic-Impact-Final-2.13.pdf

An update of the 2016 DoD study is currently underway by TechLink and is expected to be published in January 2019. In addition, TechLink is beginning the first-ever study of federal government CRADAs with U.S. industry, looking at CRADAs from three representative Army, Navy, and Air Force laboratories. TechLink is also documenting the value of DoD technology transfer to the U.S. military and to the nation's technological capabilities through a series of success stories and videos.

Partnership Intermediaries (PIAs): On p. 58, under "New/Expanded Partnership Mechanisms," the paper mentions that federal laboratories can use Partnership Intermediary Agreements to perform valuable partnerships with industry. However, there are no examples given of actual partnership intermediaries. This is a significant oversight, because the Department of Defense has been relying heavily on a national partnership intermediary, TechLink, to market its patented inventions and broker or facilitate license agreements with industry. TechLink was the first-ever partnership intermediary to be established by the federal government, created by DoD in 1999, and currently brokers over 60% of DoD license agreements nationwide. Sales of new products and services from TechLink-brokered license agreements for DoD are estimated at $2.5 billion, with the total economic output exceeding $6 billion per a recent economic-impact study. The Green Paper emphasizes the importance of establishing partnership agreements "at the speed of business." TechLink is working with the DoD labs to establish and rapidly expand "express licensing." This initiative has reduced the time it takes DoD labs to establish license agreements from 6-12 months to under 3 weeks.

I hope you will include this information in the final draft of the Green Paper. I stand ready to provide additional details at your request.

Regards,

Will Swearingen

****
Will Swearingen, PhD, CLP
Director, Special Projects and Senior Advisor
TechLink
2310 University Way, Bldg. 2-2
Bozeman, MT 59715
Tel. (406) 994-7704

From: Lesa Mitchell
To: roi
Subject: Green Paper Feedback
Date: Thursday, December 6, 2018 2:42:38 PM

When I was at the Kauffman Foundation we funded and set up iBridge Network because VCs, entrepreneurs and investors wanted a single source of access to university innovation. University Tech Transfer offices refused to use it and instead NSF or someone funded Rob Lowes technology platform which has been up and running forever and no one uses it.

We also funded iStart so that all university grad students or undergrads participating in competitions would have a single source of sharing what they are doing for purposes of investors or linking with later stage cos. We were sole funder and it was very very active so it was turned over to another Fdn who has essentially not moved it much further. As an investor I am constantly looking for entrepreneurs and finding winners or even applicants of the Rice or Baylor etc competition means I have to go to everyone website. No one is going to do that and 80% of these things have tech linked to University and probably loosely federal funding.

Lastly Desh Despande and I at Kauffman funded the creation of iCorp and sat on the board for the first two years. Again, it is imposible as an investor to easily find all iCorp invested companies. Government funded websites have horrible UI/UX (just like NIST) and therefore we are simply wasting all of these funding models thinking that investors are going to hunt them down in the archives of govt branches.

U TTTOs are the biggest problem. President Obamas first Sect of Commerce held a meeting that Aneesh Chopra, Tom Kalil, myself and others organized with University Presidents to talk about this topic. The AAU held a phone call with all University Presidents the night prior to event and said our common story is that we don't have a problem and unless there is more federal funding we don't need a change. So the university lobbyists are going to stand in the way of any change on this topic.

--
Lesa Mitchell
Managing Director, Techstars KC
Here's my calendar link to make finding time easy.
Mobile: 913-568-9531
Twitter: @lesamitchell
@techstars
Techstars.com

https://youtu.be/S-3YgWroCdo

...I walk and type

Office of the Vice Chancellor for
Research and Graduate Education
UNIVERSITY OF WISCONSIN–MADISON

January 9, 2019

RE: NIST Special Publication 1234: Return on Investment Initiative for Unleashing American Innovation, Draft Green Paper, December 2018

Submitted via e-mail to roi@nist.gov

The University of Wisconsin-Madison (UW-Madison) appreciated the opportunity to submit comments to the NIST RFI Regarding Federal Technology Transfer Authorities and Processes (Docket No. 18022019-819-01). We have reviewed the Return on Investment Initiative Draft Green Paper, December 2018, (NIST SP 1234) resulting from the RFI and ROI public forums. We wish to express our support for many of the improvements anticipated through the Intended Actions described in NIST SP 1234. Additionally, as UW-Madison is a member institution of the Council on Governmental Relations (COGR), we endorse the letter submitted by COGR and other associations on January 9, 2019.

UW-Madison supports the Intended Action 11 to establish technology entrepreneurship programs government-wide. We believe that expansion of entrepreneurial training programs such as I-Corps would produce gains at multiple levels. Such training would assist UW-Madison faculty and staff in fulfilling the Wisconsin Idea, the concept that the work we do should influence people's lives beyond the boundaries of our campus. This type of training would help our faculty and staff envision how their projects might be translated for the public's benefit. In addition, projects often involve collaborations of more than one UW-Madison faculty member or faculty from multiple institutions. Faculty may also receive funding from more than one federal agency. If those involved in these collaborations were exposed to technology entrepreneurship training, the lessons could have exponential impacts. Creation of technology entrepreneurship programs government-wide could help create networks that plant the seeds of intra-institutional, inter-institutional, or cross-disciplinary innovations.

UW-Madison also strongly supports the Intended Action to implement harmonized and consistent government-wide requirements to manage conflicts of interest. We have found the agencies' differing conflict of interest policies challenging to put into practice. While we have managed to implement multiple federal agency policies on conflict of interest, we would welcome a reduction in burden that we presume would occur as a result of consistency in COI regulation and policy.

We are also in favor of a modern, secure, and interoperable platform for reporting data on intellectual property resulting from federally-funded research and development, as described in Intended Action 13. We anticipate that consistency in requirements and system will serve to facilitate reporting and, ideally, reduce administrative burden. On a related note, we are also hopeful that Intended Action 14 to establish a federated data portal for federal R&D assets will enhance the efforts of our investigators. Having information available as described would shed light on the breadth of potential resources available to help advance ideas from lab to market.

Consistent with comments from the Council on Governmental Relations, UW-Madison has concerns regarding Strategy 2, Intended Action 9.B. Establish Research Transaction Authority (RTA). The Green Paper states that "Other Transaction Authority [OTA] allows for agreements that offer greater speed, flexibility, and accessibility in performing research…" Our institutional experience with OTA agreements is admittedly limited (even though we are a research-intensive institution), and we have found it necessary to seek advice from other institutions on handling OTA terms. OTA agreements may not be the silver bullet solution as presented in the Green Paper because of the lack of familiarity with the mechanism and the potentially troublesome terms contained therein. The Paper also indicates that the RTA "will not be used for procurement or financial assistance actions", though the bulk of federally-funded research performed at institutions of higher education is done through financial assistance (grants and cooperative agreements) and procurement (contracts). Grants, cooperative agreements, and contracts are the mechanisms most familiar to institutions of higher education and the ones that may offer a more expedient means of entering into an agreement than OTA/RTA. If the federal government wishes to establish an RTA mechanism, legislative change would be but the first step – such an authority would require significant change management. While we appreciate the desire to create a streamlined mechanism, we recommend further exploration of this Intended Action.

In conclusion, we wish to express our gratitude for NIST's thorough examination of how to improve an already strong framework provided by the Bayh-Dole Act. We believe that many of the intended actions would have a positive impact on technology transfer and look forward to continuing to work with NIST and other agencies to make progress on the Lab-to-Market cross agency priority goal. Should you have any questions, please feel free to reach out to me at norman.drinkwater@wisc.edu, (608) 262-1044, or to Kim Moreland at kmoreland@rsp.wisc.edu, (608) 262-3822.

Sincerely,

Norman R. Drinkwater, Ph.D.
Interim Vice Chancellor for Research and Graduate Education
Professor of Oncology
University of Wisconsin-Madison

Kim Moreland

Kim Moreland
Associate Vice Chancellor for Research Administration
Director, Research and Sponsored Programs
University of Wisconsin-Madison

WARF
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warf.org

January 9, 2019

RE: NIST Special Publication 1234; ROI Draft Green Paper, December 2018

Via email: roi@nist.gov

The Wisconsin Alumni Research Foundation ("WARF") appreciates the opportunity to respond to the Return on Investment Initiative ("ROI") Green Paper issued by the National Institute of Standards and Technology ("NIST") on December 6, 2018.

WARF is aware of the comments filed by UW-Madison in response to the Green Paper and wishes to associate itself with these comments.

Background about WARF and its Relationship with the University of Wisconsin-Madison ("UW-Madison")

WARF, a nonprofit foundation incorporated in 1925, has a founding purpose "to promote, encourage, and aid scientific investigation and research at and within the University of Wisconsin-Madison." In pursuit of that mission we have built an investment portfolio valued at $2.8 billion as of 2018, which over ninety-three years has funded more than $2.6 billion in research grants to UW-Madison when adjusted for inflation. WARF also serves as the designated technology transfer office for UW-Madison, and in that capacity we have acquired more than 3,000 patents, including 1,900 active patents and an additional 400 invention disclosures and 55 revenue-generating licenses each year. All of WARF's efforts are devoted to furthering the historic outreach mission of our state university known as the "Wisconsin Idea."

Sincerely,

Erik Iverson
Managing Director

Michael Falk
General Counsel

WARF
Wisconsin Alumni Research Foundation

P: 608-960-9850

614 Walnut Street, 13th Floor
Madison, WI 53726
warf.org

January 9, 2019

RE: NIST Special Publication 1234; ROI Draft Green Paper, December 2018

Via email: roi@nist.gov

Wisconsin Alumni Research Foundation Response to "Return on Investment Initiative for Unleashing American Innovation"

The Wisconsin Alumni Research Foundation ("WARF") appreciates the opportunity to respond to the Return on Investment Initiative ("ROI") Green Paper issued by the National Institute of Standards and Technology ("NIST") on December 6, 2018. WARF wishes to once again commend NIST for responding to the Lab-to-Market Cross-Agency Priority in the President's Management Agenda by undertaking the ROI Initiative, and we thank NIST in particular for the thorough, thoughtful, and conscientious collection of feedback that informed the ROI Green Paper. Above and beyond its specific policy recommendations, the draft paper contains what might be the most comprehensive overview of the challenges facing federal technology transfer today and, indeed, perhaps the most accessible overview to date of technology transfer policies and regulatory practices. In that regard, the paper has already provided a worthwhile public service.

As stated in our response to NIST's original Request for Information ("RFI," Docket Number: 180220199-819-01) the Wisconsin Alumni Research Foundation—home to one of the oldest university patenting and licensing operations in the world—has an inherent, enduring interest in improving the transfer of technologies from the laboratory to the marketplace. For more than ninety years, we have pursued that goal in close partnership with the University of Wisconsin-Madison, whose scientific research our nonprofit mission pledges to support. Our work has also fostered strong, longstanding relationships with the state of Wisconsin and its citizens; fellow research institutions, universities, and businesses in Wisconsin; our colleagues at the Association of University Technology Managers ("AUTM"); and the various agencies and public servants of the federal government.

WARF's comments on the specific "Intended Actions" in the ROI Green Paper are driven by the same two principles stated in our RFI response: the freedom to invent and local empowerment. Researchers—the people best situated to understand the applications of their science—should be allowed the freedom to develop their technologies for the overall benefit of humankind, and universities and local businesses should be empowered to ensure the widespread, ethical distribution of the social benefits of those technologies. We find inspiration for these tenets of academic freedom and local empowerment in the Wisconsin Idea, the long tradition that the University of Wisconsin System, and by extension its supporting organizations like WARF, should strive to serve every family in our home state.

With those principles in mind, WARF appreciates and strongly concurs with NIST's stated goal of preserving the original intent of the Bayh-Dole Act, passed in 1980 and derived in part from the seminal contributions of WARF's late patent counsel Howard Bremer. We also concur with the Green Paper recommendations that would apply a regulatory framework similar to Bayh-Dole to the Stevenson-Wydler Act of 1980 and the Federal Technology Transfer Act of 1986. Such a change would allow federal laboratories and government employees to benefit from the same elegant solution that has served U.S. universities, nonprofit organizations, and small businesses so well for almost forty years. The results of Bayh-Dole have exceeded the hopes of the act's authors by providing significant social and economic benefits to the nation. Using the example of Bayh-Dole, all technology transfer can follow processes and policies that unleash innovation by trusting local experts, trusting the academic freedom of laboratory scientists, and ensuring that technology transfer professionals across the public, private, and nonprofit sectors have adequate resources to fulfill their mission.

WARF also recognizes, appreciates, and shares the goals enumerated in the Green Paper to "meet current and future economic and national security needs in a rapidly shifting technology marketplace" (p. 3) through such means as increasing industrial competitiveness, building an entrepreneurial workforce, and broadening the public accessibility of technology. We pursue those same goals in our home state in cooperation with UW-Madison, the state of Wisconsin, and industry partners, so WARF appreciates how legislation and regulation can—and should—address these pressing concerns of national interest.

However, technology transfer policy must remain dedicated to two over-arching, inter-related missions: encouraging scientific research and promoting the development of that research into world-changing innovations. The rarity of true breakthrough discoveries in science and technology, and the density of resources needed to bring ideas from the laboratory to the market, means that technology transfer professionals—and the regulations that guide them—must remain laser-focused on transforming basic research into practical applications. Between the inherent unpredictability of the scientific endeavor, the costs required for commercial development of innovative products, and the inevitable happenstance of any human enterprise, the chances that the technology transfer of any particular product might be derailed are so high that deviation from our core mission can only lead to less innovation and fewer benefits delivered to humankind. The price of a product, the location of its manufacture, or the jobs it creates will be irrelevant if that product is never developed in the first place.

In the spirit of the above statements, WARF wishes to make the following specific comments on the intended actions enumerated in the ROI Green Paper:

Intended Action 1 – Government Use License.

WARF concurs with the Green Paper recommendation to define "government use" under Bayh-Dole as "use directly by the government purpose only and not for use by a third party" (p. 29). This intended action aligns with our stated principle that policy should empower inventors to make the best decisions for licensing their intellectual property, and we thank NIST for recognizing the importance of clarifying the purpose of a government use license. We also wish to reiterate those comments from RFI respondents, as summarized in the Green Paper (p. 27-8), who argued that government use licensing for the purchase of discounted products or to otherwise intervene in the post-commercialization consumer market would have a negative effect on return on investment. The possibility that a government agency might use its license for distribution to a third party has had a chilling effect on the willingness of private companies to invest in and develop federally funded intellectual property, and applying the government use license to such purposes would have other unanticipated complications and cancel out any benefits.

In terms of implementation, we ask that regulations specify that the royalty-free government use license be initiated by a government agency. Consider, as an example, a licensee that refuses to pay a full royalty to a patent-holder on the basis that they intend to sell the licensed product to the government but then charges the government a standard, non-reduced rate. Situations like this have been known to happen and they leave the patent-holder little recourse but to pursue litigation to recoup lost revenue. NIST can guard against potential abuses by clarifying that only a government agency may implement their royalty-free license.

Intended Action 2 – March-In Rights.

WARF concurs with the Green Paper recommendation to clarify the proper use of March-In Rights and reduce the ambiguity of "reasonable terms" and "practical application" in regulatory language. The Bayh-Dole Act presumes that contractors retain the rights to their intellectual property and assumes that intellectual property can best be commercialized by giving inventors broad leeway to develop and license inventions. Commercial partners need to be certain of their position under such licenses, and these partners are reluctant to invest in development with a looming threat of government intervention. March-In Rights exist as a safeguard to ensure that contractors fulfill their responsibility to bring patents to market—not as a means for government agencies to assume that responsibility themselves. The fact that March-In Rights have never been exercised should not be a source of criticism but instead seen as primary evidence for the success that grantees and contractors have had in fulfilling the goals of the Bayh-Dole Act and implementing its provisions. As stated in the Green Paper, "march-in rights should not be used as a mechanism to control or regulate the market price of goods and services" (p. 33).

On that last point, extending March-In Rights for these purposes would demand that patent-holders fulfill obligations that are not only outside their purview as inventors but that could bring separate sets of government regulations into conflict. Under the Bayh-Dole Act, federally funded inventors must fulfill four specific obligations (as enumerated on p. 30 of the Green Paper) or else a government agency will march in to ensure those obligations are met. By marching in for the purpose of controlling prices, therefore, the government would be indicating that patent-holders have an obligation to control prices. While a licensing agreement that dictates or attempts to influence a product's price may not, in and of itself, constitute price fixing under the law, requiring a patent-holder to pursue lower prices would open the door to antitrust scrutiny. In other words, federal contractors would be put in a position to choose between compromising their intellectual property rights or engaging in anti-competitive practices. Such an outcome would not serve the interests of patent-holders, licensees, the government, or the public, and could upend the proven success of Bayh-Dole. For these reasons, WARF emphasizes its appreciation to NIST for recognizing the importance of clarifying March-In Rights.

Intended Action 3 – Preference for U.S. Manufacturing.

WARF welcomes the recommendation to streamline and implement a uniform, government-wide process for regulating the U.S. manufacturing preference mandated by Bayh-Dole. We strongly urge NIST not to expand the U.S. manufacturing preference to non-exclusive licensing. To consider the problem that either a complicated waiver process or an expanded preference would cause, consider the central challenge that patent-holders face when commercializing their technology. Universities and federal laboratories—by their design—lack the capacity to manufacture products. Foundational innovations—by their very nature—have yet to be manufactured at all. If someone already knew how to make an innovative product, it would not be a true innovation. Technology transfer offices, therefore, must either find a way to develop a new manufacturing capacity through a partnership with a startup company, or convince an existing company that developing a new manufacturing process would be a profitable endeavor to undertake. Choosing the most effective manufacturing partner can be a crucial factor in determining the success or failure of a licensed product, and today's interconnected global economy increases the options for finding an optimal relationship. Having more options leads to higher odds of success and a higher return on investment.

In the case of startups, new companies formed to develop federally funded inventions will most often be founded in close proximity to the inventor. Local connections increase the odds of success and both the inventors and the communities in which they live have strong incentives to develop their local economies. In these circumstances, having to complete a waiver process can only hinder commercial development that will benefit the government's return on investment as well as benefiting domestic production. For a variety of reasons, impediments against startup creation can become insurmountable, whether because of insufficient capital, the burdens of regulation, limitations in necessary infrastructure or workforce skills, or any of a number of other well-documented hurdles that a new business must overcome.

If a startup company proves not to be a viable alternative, then inventors must license their patents to an existing company, in which case the struggle to find a willing partner can be long and difficult. This is the process that extends across the gap so often called the "valley of death" between federal funding and private investment. When traversing the valley, technology transfer offices do not necessarily seek out exclusive licensing agreements, but we recognize the importance of exclusivity as an incentive to attract private investors. Many companies will only justify the risk of commercial development if they have an assurance of exclusivity for at least some period of time.

In those circumstances where a non-exclusive agreement can be reached, technology transfer offices can use multiple licenses to achieve, as described by the Green Paper, "a balance between encouraging other countries to open their markets for American businesses and protecting American taxpayers' interests in United States Government-funded technologies" (p. 36). A technology transfer office could license a foreign company while leaving open the opportunity for one (or more) domestic companies to step up, or vice versa. Exclusivity should also not be understood as static. Without a strict U.S. manufacturing requirement, companies could take advantage of an initially non-exclusive license to test a new product in existing facilities overseas. If successful, they could then convert their agreement to an exclusive license, build a new facility, and bring the jobs home to the U.S. for a net increase in domestic productivity. In any event, the potential for failure in the commercialization process means that patent-holders must seize the opportunities presented to them or risk losing the chance to bring their intellectual property to market. More flexibility means more opportunities.

In sum, federally funded inventors have every incentive to choose a local opportunity to commercialize their intellectual property. When they chose an exclusive license, or a license to a foreign company, they do so out of careful consideration over how to maximize the chances of success—to maximize their own return on investment as well as that of their government funding agency. Further, individual non-exclusive licenses cannot be evaluated in isolation because by definition a non-exclusive license represents a single, incomplete portion of a non-exclusive strategy. To fulfill the goal of strengthening the American manufacturing base, we encourage the government to focus on ways to drive the creation of new companies and not on restricting the flexibility of inventors doing all they can to further the success of federally funded inventions.

For these reasons, we propose that the government establish a regulatory framework similar to the one that has been so successful in the exercise of March-In Rights. Rather than requiring contractors to navigate a waiver process, the government should presume that patent-holders have chosen their licensees for well-considered reasons based on in-depth knowledge about the challenges of commercial development, the potential market for their products, and their responsibility to fulfill statutory requirements. As with the march-in petitions reviewed by the National Institutes of Health over the years, a similar process for the preference for U.S. manufacturing would not prevent U.S. companies from filing complaints or prevent the government from evaluating potential abuses. We have reason to believe that such abuses would be rare. WARF understands the national interest to protect and promote domestic manufacturing, but placing the burden on patent-holders to demonstrate substantial domestic production on every one of their licenses sets a high bar, one that will hinder, rather than advance, return on investment.

Intended Action 7 – Presumption of Government Rights to Employee Inventions.

As a university supporting organization, not a government agency, WARF defers to the federal government in determining the assignment of rights to its employees. That said, WARF continues to be unique among U.S. universities in presuming individual inventors own their intellectual property, and we stand by the record of that policy. Our nine decades of history have shown that empowering individuals provides the highest level of adaptability and expertise to promote commercialization. We believe that offering the same rights to government inventors would do much to accomplish the entrepreneurial goals of the ROI initiative.

Intended Action 9 – New/Expanded Partnership Mechanisms.

WARF shares the concerns expressed by AUTM and COGR regarding the expansion of Other Transaction Authority agreements through the establishment of a Research Transaction Authority. The Office of the Vice Chancellor for Research and Graduate Education at UW-Madison has expressed similar concerns and, as indicated in our addendum to their Green Paper response, WARF associates itself with our university's statement and, in particular, to their comments on this Intended Action.

Intended Action 10 – Technology Maturation Funding.

WARF appreciates NIST highlighting the importance of earmarked federal funding specifically for technology transfer services. While we understand the need for the ROI initiative to assume a revenue neutral stance, we hope that Congress and federal agencies will see fit to allocate more resources to federal laboratories and contractors for patenting and licensing. Technology transfer deserves a dedicated revenue stream. Allowing grantees the flexibility to use some R&D funds for patenting, and communicating with the Small Business Administration about improving SBIR/STTR funds, can only be a step in the right direction.

Intended Action 11 – Technology Entrepreneurship Programs.

WARF welcomes the continued expansion of entrepreneurial programs and a review of best practices to build on the success of NSF's I-Corps program. As a supporting organization for a university, we have firsthand knowledge of the importance of education and training success—whether academic, technical, or professional.

Intended Action 13 – Federal IP Data Reporting System(s).
Intended Action 14 – Access to Federal R&D Assets.

WARF eagerly anticipates the arrival of "a modern, secure, interoperable platform for reporting data" that can implement "consistent and streamlined government-wide regulatory requirements and practices" (p. 122). As the Green Paper rightly notes, the existing platforms—most notably iEdison—have long been outdated and do not offer a universal solution for cross-agency data collection. A modernized, user-friendly system with fewer glitches and partitions will be welcomed by all technology transfer offices and their staff members. We would still emphasize that building an effective reporting system is not just a matter of technology but about the reporting requirements themselves. On a number of occasions WARF staff have attempted to enter data into iEdison only to find that the system requires a field that cannot be applied to the license or patent at hand, thus making the electronic form impossible to submit. The replacement for iEdison should therefore be built on simple reporting categories that fulfill the statutory requirements in a straightforward, intuitive, and universally applicable way.

We offer similar feedback for the proposed "federated data portal" to provide access to R&D assets. Such a portal could be a valuable resource for technology transfer, but usability and accessibility should be simplified for those who will be asked to supply the data. WARF, like most technology transfer offices, already compiles technology summaries and other documents on our patenting and licensing activities. We design these resources with specific business purposes in mind and for distribution to researchers, inventors, industry connections and other partners. Providing this information in our existing formats can be accomplished without too much effort, while a portal that required reformatting or re-entry would be burdensome and perhaps prohibitive. For requirement reporting and the asset portal, WARF asks that new functionalities not lead to new or more complicated requirements for reporting or data collection.

Intended Action 15 – Benchmarking and Metrics.

The MIT RFI response on benchmarking resonated with WARF. "There is no single, obvious way to measure the success of tech transfer that everyone has somehow been missing," and "at the same time, metrics should not be altered lightly because stability is needed to make comparisons over time" (p. 113). In an information age awash with a seemingly infinite supply of daily information, the challenge of metrics is not to reinvent the wheel but to devise new ways of understanding the resources that we, as an industry, already produce. WARF recommends that NIST work closely with our colleagues at AUTM to determine best practices in this area. AUTM has been tracking the technology transfer industry for decades now and has more experience than any other organization in wrestling with how to measure what we do in ways that are accurate, insightful, useful, and consistent all at the same time. We also appreciate the Green Paper's emphasis on "broad-based R&D outcome and impact metrics," which we read within the context of defining ROI in a way that "emphasizes the underlying social and public mission inherent in the development of Federal research into products and services benefiting American taxpayers" (p. 21). Benchmarking and metrics can be essential tools in helping our industry serve its social and public mission, but we hope that a focus on measurement will not become an end itself that detracts from our core purpose in technology transfer. WARF looks forward to collaborating with NIST and AUTM in developing a mission-driven formulation of metrics.

In addition to the specific comments enumerated above, WARF extends its appreciation for the strategy NIST has outlined in the Green Paper. Taken as a whole, the intended actions have the potential to ease regulatory burdens for our colleagues at federal laboratories, simplify processes, and bring the implementation of Stevenson-Wydler more in line with Bayh-Dole regulations. Attempts to streamline, modernize, and use university technology transfer as a model for federal laboratories can only have a positive effect on the government's return on investment.

In conclusion, WARF congratulates NIST on the insights reflected in the Green Paper, the time and care put into its creation, and for the overall effort to collect the lessons learned since the passage of Bayh-Dole to build a better technology transfer future. At WARF, we believe the future must be built on history. We were founded in 1925 when UW Professor Harry Steenbock, looking to ensure that science developed in his lab would benefit Wisconsin industry and Wisconsin's university, discovered that university administrators were reluctant to take on the financial and political risks of commercializing research. Instead, Steenbock collaborated with two of his deans and a handful of UW alumni to form the Wisconsin Alumni Research Foundation as an independent nonprofit corporation. WARF's statutory purpose, still in effect today, is not to manage intellectual property but "to promote, encourage and aid scientific investigation and research at and within the University of Wisconsin-Madison" and "to provide or assist in providing means and machinery by which their scientific discoveries, inventions and processes may be developed for the overall benefit of humankind." In 2018, we believe that mission, and the national mission of federal technology transfer, can still be served with Steenbock's combination of academic freedom, the removal of bureaucratic roadblocks, and an investment in the future of scientific discovery.

Sincerely,

Michael Falk

Erik Iverson
Managing Director

Michael Falk
General Counsel

Office of the Vice Chancellor for
Research and Graduate Education
UNIVERSITY OF WISCONSIN–MADISON

January 9, 2019

RE: NIST Special Publication 1234: Return on Investment Initiative for Unleashing American Innovation, Draft Green Paper, December 2018

Submitted via e-mail to roi@nist.gov

The University of Wisconsin-Madison (UW-Madison) appreciates the opportunity to respond to the Return on Investment Initiative Green Paper issued by the National Institute of Standards and Technology on December 6, 2018.

UW-Madison is aware of the comments filed by the Wisconsin Alumni Research Foundation (WARF) in response to the Green Paper and wishes to associate itself with these comments.

Background about UW-Madison and its relationship with the Wisconsin Alumni Research Foundation

UW-Madison was founded in 1848 and was among the first group of land-grant universities in 1862. As Wisconsin's flagship university, UW-Madison prides itself on its "firsts." Among our "firsts" was the discovery in 1924, by Professor Harry Steenbock, of methods to enrich food with vitamin D. It was this "first" that precipitated the creation of the Wisconsin Alumni Research Foundation (WARF). Since 1925, WARF has managed UW-Madison's patents and the resulting revenue, helping the University become a top-tier research institution.

UW-Madison's achievements are inextricably linked to WARF's support. WARF has sponsored several dozen WARF Named Professorships, providing research funding to faculty from a variety of disciplines. WARF has contributed to UW2020, an effort to stimulate highly innovative and groundbreaking research. WARF and UW-Madison have partnered on Discovery to Product, an initiative focused on entrepreneurship and providing faculty, staff, and students with mentorship and resources to translate their ideas into commercial products and services. These, and other, efforts have enabled WARF and UW-Madison to make vital contributions to the Wisconsin economy and to ensure that federally-supported inventions find their way to the marketplace. WARF plays an integral role in assisting UW-Madison in fulfilling the Wisconsin Idea – that the work of the University goes beyond the boundaries of the classroom and impacts the world.

Sincerely,

Kim Moreland

Norman R. Drinkwater, Ph.D.
Interim Vice Chancellor for Research
and Graduate Education
Professor of Oncology

Kim Moreland
Assoc. Vice Chancellor for Research Administration
Director, Research and Sponsored Programs

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333 Bascom Hall 500 Lincoln Drive Madison, Wisconsin 53706 608-262-1044

Strategy	Intended Action	Synopsis	Pro	Con	Suggestions

b5

b5

From: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/CN=OD/CN=ROHRBAUM]
Sent: 3/21/2017 10:27:11 PM
To: Mowatt, Michael (NIH/NIAID) [E] [/O=NIH/OU=NIHEXCHANGE/cn=NIAID/cn=MMOWATT]
Subject: Re: [Non-DoD Source] FW: Lawmakers urge US Army not to issue exclusive license to Sanofi for a Zika vaccine (UNCLASSIFIED)

Sure

Sent from my iPhone

> On Mar 21, 2017, at 5:44 PM, Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov> wrote:
>
> No major developments - happy to bring you up to speed.
>
> Will you attend the 9 am meeting with Michael tomorrow? We can talk afterward if you can spare a few minutes.
>
> -----Original Message-----
> From: Rohrbaugh, Mark (NIH/OD) [E]
> Sent: Tuesday, March 21, 2017 2:42 PM
> To: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
> Subject: RE: [Non-DoD Source] FW: Lawmakers urge US Army not to issue exclusive license to Sanofi for a Zika vaccine (UNCLASSIFIED)
>
> Mike:
>
> Anything new on this? Anything that would affect NIAID's std procedures. Please call if there is something. No rush, just checking.
>
> Thanks
> Mark
> 301-435-4485
> -----Original Message-----
> From: Mowatt, Michael (NIH/NIAID) [E]
> Sent: Monday, March 13, 2017 10:18 AM
> To: 'b6 USARMY MEDCOM USAMRMC (US)' b6
> Cc: Rohrbaugh, Mark (NIH/OD) [E] <RohrBauM@OD.NIH.GOV>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
> Subject: RE: [Non-DoD Source] FW: Lawmakers urge US Army not to issue exclusive license to Sanofi for a Zika vaccine (UNCLASSIFIED)
>
> b6
>
> Thanks again for your time last week. Our conversation was timely.
>
> I was just invited to a call with HHS ASPR, including BARDA, and others from NIAID. I notice that b6 and b6 (WRAIR, correct?) are also on the call with NIAID's lead inventors for the ZIKV DNA vaccine.
>
> I thought you should know about this; I've included Mark as well, though I notice he is out of the office until later this week.
>
> I know nothing about the call other than what was provided:
>
> 1. "Description: This call is to discuss the congressional letter on Zika vaccine licensing, since multiple ZIG partners will ultimately be touched by the issue (exclusive vs limited licenses)."
> 2.15 Feb 2017 letter from Congress to Army 3. https://www.nytimes.com/2017/03/10/opinion/bernie-sanders-trump-should-avoid-a-bad-zika-deal.html?emc=edit_th_20170311&nl=todayheadlines&nlid=44329299&_r=1
>
> I'm home today b6 but will participate in the call.
>
> Let me know if you want to talk: b6 is my mobile.
>
> Otherwise, I'll update later.
>
> Thanks,
>
> Mike
>
> -----Original Message-----
> From: b6 USARMY MEDCOM USAMRMC (US) b6

> Sent: Monday, March 06, 2017 11:38 AM
> To: Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>
> Subject: RE: [Non-DoD Source] FW: Lawmakers urge US Army not to issue exclusive license to Sanofi for a Zika vaccine (UNCLASSIFIED)
>
> Classification: UNCLASSIFIED
> Caveats: NONE
>
> yes
>
> Thanks,
> b6
> Web: https://technologytransfer.detrick.army.mil
>
>
>
> -----Original Message-----
> From: Mowatt, Michael (NIH/NIAID) [E] [mailto:MMOWATT@niaid.nih.gov]
> Sent: Monday, March 06, 2017 11:32 AM
> To: b6 USARMY MEDCOM USAMRMC (US)
> Subject: Re: [Non-DoD Source] FW: Lawmakers urge US Army not to issue exclusive license to Sanofi for a Zika vaccine (UNCLASSIFIED)
>
> All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.
>
>
>
>
> ----
>
> This Thu at 2 pm is good. I'll call you then.
>
> Is b6 the best number?
>
>> On Mar 6, 2017, at 11:04 AM, b6 USARMY MEDCOM USAMRMC (US) b6 wrote:
>>
>> Classification: UNCLASSIFIED
>> Caveats: NONE
>>
>> Mike,
>> How would Thursday at 2 Pm work?
>>
>> Thanks,
>> b6
>> ________________________________
>>
>> b6
>> Web: Caution-https://technologytransfer.detrick.army.mil
>>
>>
>>
>> -----Original Message-----
>> From: Mowatt, Michael (NIH/NIAID) [E]
>> [Caution-mailto:MMOWATT@niaid.nih.gov]
>> Sent: Friday, March 03, 2017 12:03 PM
>> To: b6 USARMY MEDCOM USAMRMC (US)
>> Subject: [Non-DoD Source] FW: Lawmakers urge US Army not to issue
>> exclusive license to Sanofi for a Zika vaccine
>>
>> All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.
>>
>>
>> ________________________________

>>
>>
>>
>>
>> Hi b6
>>
>>
>>
>> Checking back with you on this.
>>
>>
>>
>> No rush, but I'd like to set some time to chat in the next couple weeks or whenever you can spare it.
>>
>>
>>
>> Please let me know.
>>
>>
>>
>> Cheers,
>>
>>
>>
>> Mike
>>
>> 301 496-2644
>>
>>
>>
>> From: Mowatt, Michael (NIH/NIAID) [E]
>> Sent: Sunday, February 26, 2017 9:01 PM
>> To: b6 USARMY MEDCOM USAMRMC (US)'
>> b6
>> Subject: Lawmakers urge US Army not to issue exclusive license to
>> Sanofi for a Zika vaccine
>>
>>
>>
>> Hi b6
>>
>>
>>
>> This article reminded me that it's been awhile since we spoke. I imagine you've been pretty busy!
>>
>>
>>
>> Can you spare a few minutes this week to chat about this? We have a few licensing deals on the horizon, and your perspectives on this one would be helpful. 15 to 30 minutes should do.
>>
>>
>>
>> Thanks for whatever time you can spare.
>>
>>
>>
>> Regards,
>>
>>
>>
>> Mike
>>
>> Lawmakers urge US Army not to issue exclusive license to Sanofi for a
>> Zika vaccine
>>
>> Caution-Caution-https://www.statnews.com/wp-content/uploads/2016/09/ZikaTexas_GettyImages-521164272-645x645.jpgJohn Moore/Getty Images Mosquitos caught for testing for Zika and other mosquito-borne diseases.
>>
>> ByEd Silverman <
>> Caution-Caution-https://www.statnews.com/staff/ed-silverman/ >
>> @Pharmalot < Caution-Caution-https://twitter.com/Pharmalot >
>>
>> February 22, 2017
>>
>> Nearly a dozen members of Congress are urging the US Army not to issue an exclusive license to Sanofi Pasteur to develop a vaccine for the Zika virus over concerns the product may be priced too high for many Americans, even though it was developed with taxpayer funds.

>>

>> “In order to ensure that the investment made by taxpayers was worthwhile, it is critical that we ensure the vaccine to prevent against the Zika virus is accessible to anyone who requires it,” the lawmakers wrote on Wednesday in aletter < Caution-Caution-http://freepdfhosting.com/3d5a7bf154.pdf > to Robert Speer, the Acting Secretary of the Army.

>>

>> But if the Army does proceed, the lawmakers implored Speer to issue a limited license and impose requirements that allow the federal government to intervene if the drug maker sets a price that “would make it accessible to millions of Americans who need access to a vaccine they paid to develop.” The letter was signed by 11 House Democrats.

>>

>> The move comes after the military last Decemberrevealed < Caution-Caution-https://www.gpo.gov/fdsys/pkg/FR-2016-12-09/pdf/2016-29516.pdf > plans to award the company a license to a pair of government patents. That followed months of mounting alarm among public health officials over the spread of Zika, the mosquito-borne virus that can cause birth defects. At the same time, there is speculation that the market for such a vaccine may become quite lucrative.

>>

>> The government, however, has not disclosed specifics about the license. We do know that Sanofi Pasteur, which is one of the world’s biggest vaccine makers and a unit of the French pharmaceutical company, was awarded a $43.2 million grant by the Biomedical Advanced Research and Development Authority and also has aco-development < Caution-Caution-https://www.defense.gov/News/Article/Article/830751/army-researchers-sanofi-pasteur-to-co-develop-zika-virus-vaccine > deal with the Walter Reed Army Institute of Research.

>>

>> The lack of information prompted advocacy groups to complain to the Army, expressing concerns that the vaccine may be priced out of reach for many Americans, who helped fund the invention in the first place.

>>

>> A Zika vaccine is being developed at warp speed, but will there be a
>> market for it? <
>> Caution-Caution-https://www.statnews.com/2016/12/05/zika-vaccine-devel
>> opment-market/ >

>>

>>

>>

>> For instance, Knowledge Ecology International, a group that tracks access to medicines,asked < Caution-Caution-http://keionline.org/sites/default/files/KEI-request-for-information-zika-license-12-9-2016.pdf > the Army Medical Research and Materiel Command for information about the terms, such as how long the license would run, how much the government has spent, royalty rates, and pricing. The group made a point of citing federal law indicating exclusive licensing should be made only to serve a public benefit.

>>

>> A KEI spokesman says request for information have not yet been fulfilled.

>>

>> Incomments < Caution-Caution-https://www.doctorswithoutborders.org/sites/usa/files/msf_comments_to_fr_notice_re_zika_vaccine_candidate_licensing.pdf > filed last month to the US Army, Doctors Without Borders argued that an exclusive license will give Sanofi “a monopoly in the research, manufacturing and sale of the technology.” The advocacy group added that an exclusive license is no guarantee that all populations in need will be served and that Sanofi would be free to market to the most profitable markets.

>>

>> We asked the US Army for comment and will update you accordingly.

>>

>> A Sanofi Pasteur spokeswoman wrote us that the company is “well positioned” to clinically develop the vaccine and is “capable of making it available to those areas that need it most.” She also repeated what was told us two months ago – the vaccine maker has not yet created a specific commercial plan and could not say what price may eventually be charged or when the vaccine might become available. Late-stage testing has not begun. She did say the company expects to ask BARDA for more funding.

>>

>> In a recent email exchange, Rachel Sachs, an associate professor at the Washington University School of Law, wrote us that “Sanofi may also gain additional collateral benefits associated with the vaccine that make [the] argument [by the advocacy groups] even stronger. The government may choose to stockpile doses of the vaccine, or purchase it in bulk for military service members overseas. Where the government is acting as purchaser, the ‘paying twice’ argument becomes clear: the government is paying for the clinical trials and may later be purchasing the vaccine at a monopoly price.”

>>

>>

>>

>> Michael R. Mowatt, Ph.D.

>>

>> Director, Technology Transfer and Intellectual Property Office

>>

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>> National Institute of Allergy and Infectious Diseases

>>

>> National Institutes of Health

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>> U.S. Department of Health and Human Services

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